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**HCFA Rulings**

**Department of Health and  
Human Services  
Health Care Financing  
Administration**

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**Ruling No. 98-1**

**Date: December 1998**

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**Health Care Financing Administration (HCFA) Rulings** are decisions of the Administrator that serve as precedent final opinions and orders and statements of policy and interpretation. They provide clarification and interpretation of complex or ambiguous provisions of the law or regulations relating to Medicare, Medicaid, Utilization and Quality Control Peer Review, private health insurance, and related matters.

**HCFA Rulings** are binding on all HCFA components, Medicare contractors, the Provider Reimbursement Review Board, the Medicare Geographic Classification Review Board, the Departmental Appeals Board, and Administrative Law Judges (ALJs) who hear Medicare

appeals. These Rulings promote consistency in interpretation of policy and adjudication of disputes.

This Ruling states the policy of the Health Care Financing Administration regarding the appropriate administrative appeals process the Medicare carrier must provide to physicians, non-physician practitioners, and to certain entities that receive reassigned benefits from physicians and non-physician practitioners. This appeals process will be available to a physician or entity that (i) has received reassigned benefits; (ii) has been denied enrollment in the Medicare program or had Medicare billing privileges revoked; and (iii) is not eligible to use the appeals procedures in 42 CFR part 498.

#### **MEDICARE PROGRAM**

Medicare Supplementary Medical Insurance (Part B)

THE ADMINISTRATIVE APPEALS PROCESS FOR PHYSICIANS,  
NON-PHYSICIAN PRACTITIONERS, AND ENTITIES THAT RECEIVE  
REASSIGNED BENEFITS AND THAT ARE NOT PROVIDED APPEAL RIGHTS  
UNDER 42 CFR PART 498

**HELD:** A physician, non-physician practitioner or entity that receives reassigned benefits from physicians and non-physician practitioners, and that is not already included within the definition of a provider or supplier (or a prospective provider or a prospective supplier) under 42 CFR 498.2, will be accorded administrative appeal rights as set forth in this Ruling. Physicians, non-physician practitioners, and entities aggrieved by a decision denying enrollment in Medicare or revoking Medicare billing privileges may pursue the administrative appeals process described herein. This Ruling establishes the exclusive administrative procedures for those physicians, non-physician practitioners, and entities.

**CITATIONS:** Sections 1833(e), 1842(b)(6), 1842(r), 1861(r), and 1862(e)(1) of the Social Security Act (42 U.S.C. sections 13951(e), 1395u(b)(6), 1395u(r), 1395x(r), 1395y(e)(1)), 42 CFR sections 420.204, 424.73, 424.80, and 1001.1901.

## **BACKGROUND**

### A. Unique Physician Identifier Number (UPIN) and Billing Number Systems

In 1986, the Congress directed the Secretary of Health and Human Services to develop a system to identify "each physician

who furnishes services" for which payment may be made under the Social Security Act (the Act). (See Consolidated Omnibus Budget Reconciliation Act of 1985, Pub. L. 99-272, section 9202(g) (1986); now codified at section 1842(r) of the Act (42 U.S.C. 1395u(r))). The Secretary has established the Unique Physician Identifier Number (UPIN) system. Under this system, the Secretary collects certain identifying and background information through the Medicare General Enrollment Health Care Provider/Supplier Application (HCFA Form 855, OMB Approval No. 0938-0685).

To enroll a new physician, non-physician practitioner or entity in the Medicare Part B program, the Medicare carrier must receive completed HCFA Forms 855 and 855-R from the physician, non-physician practitioner or entity that seeks reassigned benefits. The Medicare carrier is responsible for reviewing the application to verify that the physician, non-physician practitioner or entity meets certain requirements prior to receiving a UPIN or Medicare billing number. The requirements will be referred to as "requirements" throughout this Ruling and are as follows:

- To receive a UPIN or Medicare billing number that will enable HCFA to make payment for Medicare services, the physician, non-physician practitioner or entity and/or any

owner(s), managing employee(s), contractor(s), cannot be currently excluded from the Medicare program by the Department of Health and Human Services Office of Inspector General, or from participation in the program of any other Federal agency.

- A physician must be licensed to practice medicine, and an entity must comply with the applicable State and Federal licensure and Medicare regulatory requirements. Non-physician practitioners must be legally authorized to practice in the State where he or she practices and meet all of the qualification requirements for his or her speciality as set forth in 42 CFR 410 and section 2100 of the Medicare Carriers Manual, Part 3 Claims Process (HCFA-Pub. 14-3).

- An entity must qualify as a provider or supplier of medical and health services. An entity seeking Medicare payment must be eligible to receive reassigned benefits from a physician in accordance with the Medicare reassignment statute in section 1842(b)(6) of the Act (42 U.S.C. 1395u(b)(6)).

Upon approval, HCFA assigns a UPIN that uniquely identifies the physician, non-physician practitioner or entity. The UPIN is used by the physician, non-physician practitioner or entity for each claim for services furnished to a Medicare beneficiary and is used to expedite processing

and payment for Medicare claims, including electronic transactions.

If the Medicare carrier reviews the application and determines that the requirements for obtaining a UPIN are not met, the physician, non-physician practitioner or entity will be denied enrollment in the Medicare program. For those physicians, non-physician practitioners, and entities that are enrolled already in the Medicare program but are found not to continue to meet these requirements, their billing privileges are revoked. The Medicare carrier notifies the physician, non-physician practitioner or entity by certified mail that it is not permitted to bill Medicare.

B. Unlicensed Individuals or Excluded Physicians and Non-Physician Practitioners

Physicians' and non-physician practitioners' services are a covered benefit under the Supplementary Medical Insurance Program (Part B of title XVIII of the Act). A physician is defined in section 1861(r) of the Act (42 U.S.C. 1395x(r)) and includes "a doctor of medicine or osteopathy legally authorized to practice medicine or surgery by the State in which he [sic] performs such function or action." A non-physician practitioner encompasses the following

practitioners included in section 1842(b)(18)(C) of the Act: physician assistant, nurse practitioner, clinical nurse specialist, certified nurse-midwife, clinical social worker, and clinical psychologist. Each of these practitioners is defined in section 1861 of the Act, which requires that they each be legally authorized to practice in the State where he or she furnishes services. Thus, the Act requires that physicians and non-physician practitioners meet State licensing requirements before payment can be made for reasonable and necessary physicians' and non-physician practitioners' services. Licensing information, concerning the State where a physician or non-physician practitioner is licensed and the physician's and non-physician practitioner's current eligibility to participate in the Medicare program, must be provided by the physician or non-physician practitioner or Medicare payment will not be made. (See sections 1833(e) and 1861(r) of the Act, 42 U.S.C. 13951(e) and 1395x(r)).

Section 1862(e)(1) of the Act bars payment in almost all instances for the services performed by or "at the medical direction or on the prescription of" an excluded physician and non-physician practitioner during the period the physician and non-physician practitioner is excluded. (See 42 CFR

420.204(b) and 1001.1901(b).) Moreover, unless an exception is granted by the Act, HCFA is prohibited from making any payment to a physician, non-physician practitioner or entity that has been debarred, suspended, or otherwise excluded in accordance with section 2455 of the Federal Acquisition Streamlining Act of 1994, Pub. L. 103-355.

The Office of Inspector General (OIG), in its November 1996 Report No. A-14-96-00202, identified situations in which an individual who was not properly licensed or had been excluded from participation in the Medicare program continued to file claims and receive Medicare reimbursement. Moreover, several published Federal court decisions have involved the situation whereby an individual had falsely claimed to have met State licensing requirements to act as a health care professional. To protect Medicare beneficiaries, HCFA has established enrollment procedures to ensure that individuals who seek to furnish services to Medicare beneficiaries are properly licensed and are not currently excluded from participation in the Medicare program.

C. Reassignment of Medicare Benefits

HCFA has recognized that a physician and non-physician practitioner may reassign his or her Medicare benefits (the

right to bill and receive payment from Medicare) to certain entities in some circumstances. While the form of the business arrangement may vary, if payments are appropriately reassigned from the physician and non-physician practitioner to the entity in accordance with the Medicare reassignment statute in section 1842(b)(6) of the Act, Medicare payments can be made to the entity.

Section 1842(b)(6) of the Act establishes the general principle that Medicare program payments should be made to the beneficiary or, under an assignment, to the physician or non-physician practitioner who furnishes the service. This principle was developed to ensure accountability and to prevent factoring, a practice of selling accounts receivable to a third party for Medicare payment that the Congress specifically found to be abusive. By preventing a third party from obtaining a direct payment from the Medicare program, the Congress hoped to destroy a third party's incentives to engage in abusive billing practices, or to submit claims for services that were not furnished. (See H. Rep. No. 92-231, at 104 (1971) and S. Rep. No. 92-1230, at 204 (1972).) The Congress, however, created several narrow exceptions that permit a physician and non-physician practitioner to reassign Medicare benefits to his or her employer, a facility where the service

was furnished, or to certain other entities if specific conditions are satisfied.

If an entity seeks direct Medicare payment for the services furnished by a physician or non-physician practitioner, the Medicare carrier may ask the entity to explain how the current arrangement is consistent with the Medicare reassignment statute in section 1842(b)(6) of the Act and our regulations in 42 CFR 424.73 and 424.80, and identify the specific statutory or regulatory exception that authorizes payment.

**ADMINISTRATIVE APPEALS PROCESS FOR PHYSICIANS, NON-PHYSICIAN PRACTITIONERS, AND ENTITIES WHOSE MEDICARE ENROLLMENT IS DENIED OR WHOSE BILLING NUMBER IS REVOKED**

**A. Overview**

A physician, non-physician practitioner or other entity, whose Medicare enrollment is denied or whose Medicare billing privilege is revoked, can request an appeal of that decision. This appeal procedure ensures that a physician, non-physician practitioner or entity that is not entitled to appeal rights under 42 CFR part 498 receives a fair and full opportunity to be heard.

The appeals process outlined in this Ruling is for physicians, non-physician practitioners or entities that receive reassigned benefits, and in general, is based on the existing appeals process used for suppliers of durable medical equipment, prosthetics, orthotics, or supplies (DMEPOS) at 42 CFR 405.874. The administrative appeals process includes the right to a Medicare carrier hearing before a hearing officer who was not involved with the original carrier determination and the right to seek a review before an HCFA official designated by the HCFA Administrator.

If a Medicare carrier reviews the application and finds that a physician, non-physician practitioner or entity does not meet one or more of the requirements listed under section A in the **Background** part of this Ruling, the Medicare carrier denies the application and sends a denial letter explaining the reason for the denial to the physician, non-physician practitioner or entity. The letter explains the procedures for requesting a Medicare carrier hearing.

Similarly, when a Medicare carrier discovers that a physician, non-physician practitioner or entity no longer meets one of the requirements for a billing number, the physician's, non-physician practitioner's or entity's billing number is revoked. The carrier sends the physician,

non-physician practitioner or entity a letter that explains that the billing number is revoked 15 days from the date of the letter, states why the billing number is being revoked, and informs the physician, non-physician practitioner or entity of the procedures for requesting a carrier hearing.

If a physician, non-physician practitioner or entity seeks review of the carrier's determination by filing a request for a carrier hearing, and there is a less than fully favorable decision by the hearing officer, the physician, non-physician practitioner or entity or the carrier may seek further review before an HCFA official. The decision of the HCFA official is the final administrative decision.

An initial carrier determination, a decision of a carrier hearing officer, or a decision of an HCFA official may be reopened by the carrier or hearing officer in accordance with the procedures set forth at 42 CFR 405.841 and 405.842.

If, instead of filing or completing an appeal, a physician, non-physician practitioner or entity completes a corrective action plan and provides sufficient evidence to the carrier that it has complied fully with the Medicare requirements, the carrier may reinstate the physician's, non-physician practitioner's or entity's billing number. The

carrier may pay for services furnished on or after the effective date of the reinstatement.

B. Carrier Hearing

A physician, non-physician practitioner or entity that wishes to request a carrier hearing, must file its request with the Medicare carrier within 60 days from the date of the receipt of the initial determination letter to be considered timely filed. The date the letter is received by the carrier is treated as the date of filing. Failure to timely request a carrier hearing is deemed a waiver of all rights to further administrative review. The request may be signed by the physician, non-physician practitioner or any responsible official within the entity.

If a timely request for a carrier hearing is made, a carrier hearing officer, not involved in the original determination to disallow a physician, non-physician practitioner or entity enrollment application, or to revoke a current billing number, must hold a hearing within 60 days of receipt of the appeal request, or later if requested by the physician, non-physician practitioner or entity.

The physician, non-physician practitioner, entity or the carrier may offer new evidence. The burden of persuasion is

on the physician, non-physician practitioner or entity to show that its enrollment application was incorrectly disallowed or that the revocation of its billing number was incorrect. The carrier hearing officer's determination is based upon the information presented. The hearing is a thorough, independent review of the carrier's initial determination and the entire body of evidence, including any new information submitted. The carrier hearing can be held in person or by telephone at the physician's, non-physician practitioner's or entity's request.

The hearing officer issues a written decision as soon as practicable after the hearing and forwards the decision by certified mail to HCFA, the carrier, and the physician, non-physician practitioner or entity. The decision includes (i) information about the carrier's, physician's, non-physician practitioner's or entity's further right to appeal; (ii) the address to which the written appeal must be mailed; and (iii) the date by which the appeal must be filed, that is, 60 days after the date of receipt of the decision.

A physician, non-physician practitioner, carrier or entity may appeal the carrier hearing officer's decision to HCFA for a final administrative review within 60 days after the date of receipt of the hearing officer's decision. Failure to timely

request the final administrative review by HCFA is deemed a waiver of all rights to further administrative review.

A carrier hearing officer's partial or complete reversal of a carrier's initial determination is not implemented pending the carrier's decision to appeal the reversal to HCFA, unless the carrier, in its sole discretion, and without prejudice to its right to appeal, decides to implement the reversal pending an appeal. The carrier implements a reversal if it decides not to appeal a reversal to HCFA, or the time to appeal expires. A carrier may implement a carrier hearing officer's partial reversal even if the physician, non-physician practitioner or entity has appealed the partial reversal to HCFA, or the time for the physician, non-physician practitioner or entity to file an appeal has not expired.

C. Claims Submitted Following Revocation

If a carrier finds that payment to an organization or other entity is precluded under the reassignment statute and regulations, and the billing number is revoked, subsequent claims submitted by the reassignee following revocation will be rejected. The physician or non-physician practitioner that furnished the health care service can bill the Medicare

program for payment in accordance with the applicable rules for submitting claims.

NOTE: HCFA may take the appropriate steps to collect Medicare overpayments or pursue other appropriate legal remedies.

D. HCFA Review

If a timely request for a final HCFA administrative review of the carrier hearing officer's decision is made, an HCFA official, designated by the Administrator of HCFA, issues a decision based on the decision and the record established by the carrier hearing officer. The HCFA official may supplement the record by requesting and obtaining any additional information from the carrier, physician, non-physician practitioner or entity. The HCFA official's decision is (i) issued in writing as soon as practicable after the HCFA official determines that there is sufficient information to decide the appeal (or that no additional information is forthcoming), unless the party appealing the hearing officer's decision requests a delay; (ii) is forwarded by certified mail to the carrier and the physician, non-physician practitioner or entity; and (iii) contains information that no further administrative appeals are available.

EFFECTIVE DATE

This Ruling is effective \_\_\_\_\_, 1998.

Dated: Dec. 11 1998

Nancy-Ann DeParle

Nancy-Ann Min DeParle

Administrator, Health Care

Financing Administration.







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**HCFA Rulings**

**Department of Health and  
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Section 1842(b)(6) of the Act establishes the general principle that Medicare program payments should be made to the beneficiary or, under an assignment, to the physician or non-physician practitioner who furnishes the service. This principle was developed to ensure accountability and to prevent factoring, a practice of selling accounts receivable to a third party for Medicare payment that the Congress specifically found to be abusive. By preventing a third party from obtaining a direct payment from the Medicare program, the Congress hoped to destroy a third party's incentives to engage in abusive billing practices, or to submit claims for services that were not furnished. (See H. Rep. No. 92-231, at 104 (1971) and S. Rep. No. 92-1230, at 204 (1972).) The Congress, however, created several narrow exceptions that permit a physician and non-physician practitioner to reassign Medicare benefits to his or her employer, a facility where the service

was furnished, or to certain other entities if specific conditions are satisfied.

If an entity seeks direct Medicare payment for the services furnished by a physician or non-physician practitioner, the Medicare carrier may ask the entity to explain how the current arrangement is consistent with the Medicare reassignment statute in section 1842(b)(6) of the Act and our regulations in 42 CFR 424.73 and 424.80, and identify the specific statutory or regulatory exception that authorizes payment.

**ADMINISTRATIVE APPEALS PROCESS FOR PHYSICIANS, NON-PHYSICIAN PRACTITIONERS, AND ENTITIES WHOSE MEDICARE ENROLLMENT IS DENIED OR WHOSE BILLING NUMBER IS REVOKED**

**A. Overview**

A physician, non-physician practitioner or other entity, whose Medicare enrollment is denied or whose Medicare billing privilege is revoked, can request an appeal of that decision. This appeal procedure ensures that a physician, non-physician practitioner or entity that is not entitled to appeal rights under 42 CFR part 498 receives a fair and full opportunity to be heard.

The appeals process outlined in this Ruling is for physicians, non-physician practitioners or entities that receive reassigned benefits, and in general, is based on the existing appeals process used for suppliers of durable medical equipment, prosthetics, orthotics, or supplies (DMEPOS) at 42 CFR 405.874. The administrative appeals process includes the right to a Medicare carrier hearing before a hearing officer who was not involved with the original carrier determination and the right to seek a review before an HCFA official designated by the HCFA Administrator.

If a Medicare carrier reviews the application and finds that a physician, non-physician practitioner or entity does not meet one or more of the requirements listed under section A in the **Background** part of this Ruling, the Medicare carrier denies the application and sends a denial letter explaining the reason for the denial to the physician, non-physician practitioner or entity. The letter explains the procedures for requesting a Medicare carrier hearing.

Similarly, when a Medicare carrier discovers that a physician, non-physician practitioner or entity no longer meets one of the requirements for a billing number, the physician's, non-physician practitioner's or entity's billing number is revoked. The carrier sends the physician,

non-physician practitioner or entity a letter that explains that the billing number is revoked 15 days from the date of the letter, states why the billing number is being revoked, and informs the physician, non-physician practitioner or entity of the procedures for requesting a carrier hearing.

If a physician, non-physician practitioner or entity seeks review of the carrier's determination by filing a request for a carrier hearing, and there is a less than fully favorable decision by the hearing officer, the physician, non-physician practitioner or entity or the carrier may seek further review before an HCFA official. The decision of the HCFA official is the final administrative decision.

An initial carrier determination, a decision of a carrier hearing officer, or a decision of an HCFA official may be reopened by the carrier or hearing officer in accordance with the procedures set forth at 42 CFR 405.841 and 405.842.

If, instead of filing or completing an appeal, a physician, non-physician practitioner or entity completes a corrective action plan and provides sufficient evidence to the carrier that it has complied fully with the Medicare requirements, the carrier may reinstate the physician's, non-physician practitioner's or entity's billing number. The

carrier may pay for services furnished on or after the effective date of the reinstatement.

B. Carrier Hearing

A physician, non-physician practitioner or entity that wishes to request a carrier hearing, must file its request with the Medicare carrier within 60 days from the date of the receipt of the initial determination letter to be considered timely filed. The date the letter is received by the carrier is treated as the date of filing. Failure to timely request a carrier hearing is deemed a waiver of all rights to further administrative review. The request may be signed by the physician, non-physician practitioner or any responsible official within the entity.

If a timely request for a carrier hearing is made, a carrier hearing officer, not involved in the original determination to disallow a physician, non-physician practitioner or entity enrollment application, or to revoke a current billing number, must hold a hearing within 60 days of receipt of the appeal request, or later if requested by the physician, non-physician practitioner or entity.

The physician, non-physician practitioner, entity or the carrier may offer new evidence. The burden of persuasion is

on the physician, non-physician practitioner or entity to show that its enrollment application was incorrectly disallowed or that the revocation of its billing number was incorrect. The carrier hearing officer's determination is based upon the information presented. The hearing is a thorough, independent review of the carrier's initial determination and the entire body of evidence, including any new information submitted. The carrier hearing can be held in person or by telephone at the physician's, non-physician practitioner's or entity's request.

The hearing officer issues a written decision as soon as practicable after the hearing and forwards the decision by certified mail to HCFA, the carrier, and the physician, non-physician practitioner or entity. The decision includes (i) information about the carrier's, physician's, non-physician practitioner's or entity's further right to appeal; (ii) the address to which the written appeal must be mailed; and (iii) the date by which the appeal must be filed, that is, 60 days after the date of receipt of the decision.

A physician, non-physician practitioner, carrier or entity may appeal the carrier hearing officer's decision to HCFA for a final administrative review within 60 days after the date of receipt of the hearing officer's decision. Failure to timely

request the final administrative review by HCFA is deemed a waiver of all rights to further administrative review.

A carrier hearing officer's partial or complete reversal of a carrier's initial determination is not implemented pending the carrier's decision to appeal the reversal to HCFA, unless the carrier, in its sole discretion, and without prejudice to its right to appeal, decides to implement the reversal pending an appeal. The carrier implements a reversal if it decides not to appeal a reversal to HCFA, or the time to appeal expires. A carrier may implement a carrier hearing officer's partial reversal even if the physician, non-physician practitioner or entity has appealed the partial reversal to HCFA, or the time for the physician, non-physician practitioner or entity to file an appeal has not expired.

C. Claims Submitted Following Revocation

If a carrier finds that payment to an organization or other entity is precluded under the reassignment statute and regulations, and the billing number is revoked, subsequent claims submitted by the reassignee following revocation will be rejected. The physician or non-physician practitioner that furnished the health care service can bill the Medicare

program for payment in accordance with the applicable rules for submitting claims.

NOTE: HCFA may take the appropriate steps to collect Medicare overpayments or pursue other appropriate legal remedies.

D. HCFA Review

If a timely request for a final HCFA administrative review of the carrier hearing officer's decision is made, an HCFA official, designated by the Administrator of HCFA, issues a decision based on the decision and the record established by the carrier hearing officer. The HCFA official may supplement the record by requesting and obtaining any additional information from the carrier, physician, non-physician practitioner or entity. The HCFA official's decision is (i) issued in writing as soon as practicable after the HCFA official determines that there is sufficient information to decide the appeal (or that no additional information is forthcoming), unless the party appealing the hearing officer's decision requests a delay; (ii) is forwarded by certified mail to the carrier and the physician, non-physician practitioner or entity; and (iii) contains information that no further administrative appeals are available.

**EFFECTIVE DATE**

This Ruling is effective \_\_\_\_\_, 1998.

Dated: Dec. 11 1998

Nancy-Ann DeParle

Nancy-Ann Min DeParle

Administrator, Health Care

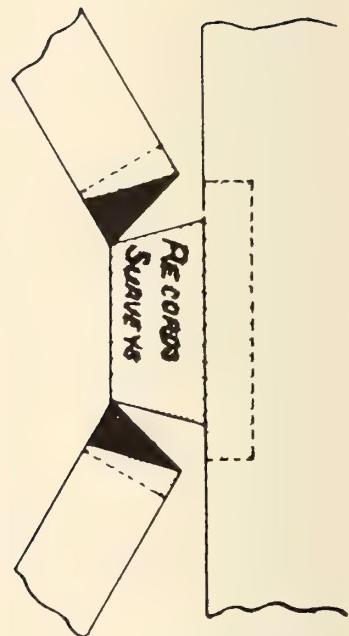
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#### HOW TO USE THESE SEPARATORS

# **HCFA Rulings**

**Department of Health  
and Human Services**

**Health Care Financing  
Administration**

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Ruling No 97-2

Date February 1997

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**HCFA Rulings** are decisions of the Administrator that serve as precedent final opinions and orders and statements of policy and interpretation. They provide clarification and interpretation of complex or ambiguous statutory or regulatory provisions relating to Medicare, Medicaid, Utilization and Quality Control Peer Review, and related matters.

**HCFA Rulings** are binding on all HCFA components, Medicare contractors, the Provider Reimbursement Review Board, the Medicare Geographic Classification Review Board, the Departmental Appeals Board, and Administrative Law Judges who hear Medicare appeals. These decisions promote consistency in interpretation of policy and adjudication of disputes.

This Ruling states the policy of the Health Care Financing Administration concerning the determination to change its interpretation of section 1886(d)(5)(F)(vi)(II) of the Social Security Act (the Act) and 42 CFR 412.106(B)(4) to follow the holdings of the United States Courts of Appeals for the Fourth, Sixth, Eighth, and Ninth Circuits. Under the new interpretation, the Medicare disproportionate share adjustment under the hospital inpatient prospective payment system will be calculated to include all inpatient hospital days of service for patients who were eligible on that day for medical assistance under a State Medicaid plan in the

Medicaid fraction, whether or not the hospital received payment for those inpatient hospital services.

**MEDICARE PROGRAM**

Hospital Insurance (Part A).

**INTERPRETATION OF MEDICAID DAYS INCLUDED IN THE MEDICARE DISPROPORTIONATE SHARE ADJUSTMENT CALCULATION**

**PURPOSE:** This Ruling announces the Health Care Financing Administration's (HCFA) determination to change its interpretation of section 1886(d)(5)(F)(vi)(II) of the Social Security Act (the Act) and 42 CFR 412.106(B)(4) to follow the holdings of the United States Courts of Appeals for the Fourth, Sixth, Eighth, and Ninth Circuits. Under the new interpretation, the Medicare disproportionate share adjustment under the hospital inpatient prospective payment system will be calculated to include all inpatient hospital days of service for patients who were eligible on that day for medical assistance under a State Medicaid plan in the Medicaid fraction, whether or not the hospital received payment for those inpatient hospital services.

**CITATIONS:** Section 1886(d)(5)(F) of the Social Security Act and 42 CFR 412.106(b)(4).

**PERTINENT HISTORY:** The Medicare disproportionate share hospital (DSH) adjustment calculation, which is set forth in section 1886(d)(5)(F) of the Act, has been the subject of a

substantial amount of litigation. The adjustment is calculated by determining a hospital's disproportionate patient percentage, which is the sum of two fractions, the Medicare fraction and the Medicaid fraction. In the Medicare fraction, the number of patient days for patients who (for those days) were entitled to both Medicare Part A and Supplemental Security Income (SSI) under Title XVI of the Act is divided by the total number of patient days for patients entitled to Medicare Part A for that same period. The Medicaid fraction consists of the number of patient days for patients who for those days "were eligible for medical assistance under a State plan approved under title XIX [Medicaid] but who were not entitled to benefits under Medicare Part A" (section 1886(d)(5)(F)(vi)(II) of the Act), divided by the total number of patient days for that same period. The Medicaid fraction is the subject of this ruling.

In implementing the calculation of the Medicaid fraction, HCFA interpreted the statutory language to include as Medicaid patient days only those days for which the hospital received Medicaid payment for inpatient hospital services. This interpretation has been considered by the courts of appeals in four judicial circuits. The initial issue in the litigation was whether HCFA should have counted days for patients who had been found to be Medicaid eligible, but who had exceeded Medicaid coverage limitations

on inpatient hospital days of service (and, consequently, no Medicaid payment was made for those days). In later cases, plaintiffs challenged HCFA's exclusion of any days of inpatient hospital services for patients who met Medicaid eligibility requirements, regardless of the reason for which no Medicaid payment was made. In each of the cases, the court declined to uphold HCFA's interpretation, reasoning that the statutory language "eligible for medical assistance" would include days on which the patient meets Medicaid eligibility criteria regardless of whether payment is made.

Although HCFA believes that its longstanding interpretation of the statutory language was a permissible reading of the statutory language, HCFA recognizes that, as a result of the adverse court rulings, this interpretation is contrary to the applicable law in four judicial circuits.

In order to ensure national uniformity in calculation of DSH adjustments, HCFA has determined that, on a prospective basis, HCFA will count in the Medicaid fraction the number of days of inpatient hospital services for patients eligible for Medicaid on that day, whether or not the hospital received payment for those inpatient hospital services. This would not include days for which no Medicaid payment was made because of the patient's spenddown liability, because an individual was not eligible for Medicaid at that point.

Pursuant to this Ruling, Medicare fiscal intermediaries will determine the amounts due and make appropriate payments through normal procedures. Claims must, of course, meet all other applicable requirements. This includes the requirement for data that are adequate to document the claimed days. The hospitals bear the burden of proof and must verify with the State that a patient was eligible for Medicaid (for some covered services) during each day of the patient's inpatient hospital stay. As the intermediaries may require, hospitals are responsible for and must furnish appropriate documentation to substantiate the number of patient days claimed. Days for patients that cannot be verified by State records to have fallen within a period wherein the patient was eligible for Medicaid cannot be counted.

We will not reopen settled cost reports based on this issue. For hospital cost reports that are settled by fiscal intermediaries on or after the effective date of this ruling, these days may be included. For hospital cost reports which have been settled prior to the effective date of this ruling, but for which the hospital has a jurisdictionally proper appeal pending on this issue pursuant to either 42 CFR 405.1811 or 42 CFR 405.1835, these days may be included for purposes of resolving the appeal.

**RULING:** For all cost reporting periods beginning on or after February 27, 1997, the Medicare disproportionate share

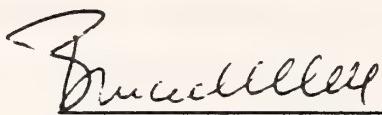
share adjustment will be determined by including in the calculation of the Medicaid fraction set forth in section 1886(d)(5)(F)(vi)(II) of the Act the additional days as set forth above.

HCFAR 97-2-6

IV. EFFECTIVE DATE

This Ruling is effective February 27, 1997.

Dated: 2/27/97



Bruce C. Vladeck  
Administrator,  
Health Care Financing  
Administration

### How to use these separators

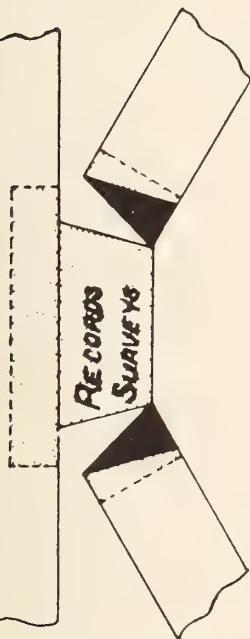
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SECOND	99	92	85	78	71	64	57	50	43	36	29	22	15	8	1
THIRD	100	93	86	79	72	65	58	51	44	37	30	23	16	9	2
FOURTH		94	87	80	73	66	59	52	45	38	31	24	17	10	3
FIFTH		95	88	81	74	67	60	53	46	39	32	25	18	11	4
SIXTH		96	89	82	75	68	61	54	47	40	33	26	19	12	5
SEVENTH		97	90	83	76	69	62	55	48	41	34	27	20	13	6





# HCFA Rulings

Department of Health  
and Human Services

Health Care Financing  
Administration

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Ruling No 97-1

Date February 1997

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HCFA Rulings are decisions of the Administrator that serve as precedent final opinions and orders and statements of policy and interpretation. They provide clarification and interpretation of complex or ambiguous provisions of the law or regulations relating to Medicare, Medicaid, Utilization and Quality Control Peer Review, and related matters.

HCFA Rulings are binding on all HCFA components, Medicare contractors, the Office of Hearings, the Medicare Geographic Classification Review Board, the Departmental Appeals Board and Administrative Law Judges who hear Medicare appeals. These Rulings promote consistency in interpretation of policy and adjudication of disputes.

This Ruling states the policy of the Health Care Financing Administration concerning the requirements for determining if Medicare payment will be made under the limitation on liability provision, section 1879 of the Social Security Act, to a provider, practitioner, or other supplier for partial hospitalization services for which Medicare payment is denied.



**MEDICARE PROGRAM**

Hospital Insurance (Part A) and Supplementary Medical Insurance (Part B)

REQUIREMENTS FOR DETERMINING LIMITATION ON LIABILITY OF A MEDICARE BENEFICIARY, PROVIDER, PRACTITIONER, OR OTHER SUPPLIER FOR PARTIAL HOSPITALIZATION SERVICES FOR WHICH MEDICARE PAYMENT IS DENIED.

PURPOSE: This Ruling states the policy of the Health Care Financing Administration concerning the requirements for determining if Medicare payment will be made under the limitation on liability provision, section 1879 of the Social Security Act, to a provider, practitioner, or other supplier for partial hospitalization services for which Medicare payment is denied.

CITATIONS: Sections 1142, 1154, 1814, 1815, 1833, 1834, 1835, 1861, 1862, 1866, and 1879 of the Social Security Act (42 U.S.C. 1320b-12, 1320c-3, 1395f, 1395g, 1395l, 1395m, 1395n, 1395x, 1395y, 1395cc, and 1395pp) and 42 CFR 411.400, 411.402, 411.404, 411.406, and HCFA Ruling 95-1.

RULING APPLICABLE TO DETERMINING LIMITATION ON LIABILITY OF  
A MEDICARE BENEFICIARY, PROVIDER, PRACTITIONER, OR OTHER  
SUPPLIER FOR PARTIAL HOSPITALIZATION SERVICES FOR WHICH  
MEDICARE PAYMENT IS DENIED

I. BACKGROUND

Section 1879 of the Social Security Act (the Act) provides financial relief to beneficiaries, providers, practitioners, and other suppliers by permitting Medicare payment to be made, or requiring refunds to be made, for certain services and items for which Medicare payment would otherwise be denied. We refer to this section of the Act as "the limitation on liability provision." The claims payment and beneficiary indemnification provisions (sections 1879(a) and (b)) of the limitation on liability provision are applicable only to claims for beneficiary items or services submitted by providers, or by practitioners and other suppliers that have taken assignment, and only to claims for services, not otherwise statutorily excluded, that are denied on the basis of section 1862(a)(1), 1862(a)(9), 1879(e), or 1879(g) of the Act. Section 1879(h) of the Act provides for refunds by the supplier to the beneficiary in the case of certain claims for medical equipment and supplies which are furnished on an assignment-related basis, and for which payment is denied. This Ruling deals primarily with section 1879(a) through (g), whereby Medicare

payment may be made, or the beneficiary may be indemnified, under certain circumstances.

The purpose of this Ruling is to provide a detailed clarification of our policy with regard to the limitation on liability provision as it applies to partial hospitalization services to ensure that Medicare payment under the policy is made in an appropriate and consistent manner. This Ruling supplements and extends HCFA Ruling 95-1.

## II. DENIALS FOR WHICH THE LIMITATION ON LIABILITY PROVISION DOES NOT APPLY

Medicare payment under the limitation on liability provision cannot be made when Medicare coverage is denied on any basis other than one of the provisions of the law specified in section I. of this Ruling. There are certain claims, however, that may appear to involve a question of medical necessity, as described in section 1862(a)(1)(A) of the Act (that is, services and items found to be not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member), but the actual Medicare payment denial is based on a statutory provision other than section 1862(a)(1)(A). Under these circumstances, Medicare payment under the limitation on liability provision cannot be made because the denial is not based on one of the statutory provisions specified in section I. of this Ruling.

A particular situation in which protection under the limitation on liability provision cannot be afforded is in the case of certain partial hospitalization services coverage denials in which Medicare payment is denied on the basis of either section 1861(ff) of the Act or section 1835(a)(2)(F) of the Act.

If an individual beneficiary does not qualify for the partial hospitalization services benefit because the certification requirements of section 1835(a)(2)(F) are not met (e.g., the beneficiary would not require inpatient psychiatric care in the absence of such partial hospitalization services), then all items and services billed as partial hospitalization services must be denied under section 1835(a)(2)(F).

If the certification requirements of section 1835(a)(2)(F) are met, then, in adjudicating a partial hospitalization services claim for items or services furnished to the qualified beneficiary, an intermediary must first apply the criteria of section 1861(ff)(1)-(3) to determine whether the particular items or services furnished to that beneficiary meet the definition of partial hospitalization services, particularly the specific definitions of items and services in section 1861(ff)(2)(A)-(I). If, thereupon, the items or services do not meet the definition of partial hospitalization services (e.g., the items or services furnished do not qualify for

the partial hospitalization services benefit under section 1861(ff)(2)(A)-(I), or the partial hospitalization services program does not qualify for the partial hospitalization services benefit under section 1861(ff)(3)), then all those items and services billed as partial hospitalization services must be denied under section 1861(ff). These denials may be referred to as "technical denials" in contradistinction to "medical necessity denials."

### III. DENIALS FOR WHICH THE LIMITATION ON LIABILITY PROVISION DOES APPLY

If the certification requirements of section 1835(a)(2)(F) are met and the items or services furnished to the qualified beneficiary qualify as partial hospitalization services under section 1861(ff), then, in adjudicating a partial hospitalization services claim, an intermediary must apply the medical necessity criteria in section 1861(ff)(2) (following section 1861(ff)(2)(I)) to determine whether the items or services furnished qualify for the partial hospitalization services benefit as being "reasonable and necessary for the diagnosis or active treatment of the individual's condition and functional level and to prevent relapse or hospitalization...", that is, whether the items or services are "medically necessary." If, thereupon, the items or services furnished do not qualify for the partial hospitalization services benefit because they were not medically necessary, then they must be denied under section

1862(a)(1)(A) of the Act. Such a medical necessity denial would not be denied under section 1861(ff)(2); rather, it would be denied under section 1862(a)(1)(A), which is the medical necessity exclusion of title XVIII, since Congress has not indicated an intent to give medical necessity denials of partial hospitalization services claims any less section 1879 protection than other types of medical necessity denials. Therefore, partial hospitalization services which are otherwise covered under section 1835(a)(2) and under section 1861(ff) can be denied under section 1862(a)(1)(A) for lack of medical necessity, in which case the protection under the limitation on liability provision can be afforded if all the elements are satisfied.

#### IV. DEFINITION OF "QUALIFYING"

When reference is made to a beneficiary qualifying for the partial hospitalization services benefit, this refers to provisions of the law which condition coverage upon the needs of the individual Medicare beneficiary. In order for a beneficiary to qualify for the partial hospitalization services benefit, the beneficiary first must require at a minimum the partial hospitalization level of care. The beneficiary cannot qualify under section 1835(a)(2)(F) unless he or she would require inpatient psychiatric care in the absence of partial hospitalization services, the services are based on an individualized written plan for

furnishing such services which has been established by a physician and is reviewed periodically by a physician, and the services were furnished while the individual was under the care of a physician. The beneficiary's physician must certify the beneficiary's need for partial hospitalization services. If the beneficiary meets the criteria of section 1835(a)(2)(F), then the beneficiary must also qualify for the specific partial hospitalization Services benefit actually furnished. The beneficiary cannot qualify under section 1861(ff)(2) unless he or she has a need, for the diagnosis or active treatment of his or her condition, for one or more of the covered partial hospitalization services items and services (which are defined in section 1861(ff)(2)(A)-(I)), which items and/or services would be reasonably expected to improve or maintain the beneficiary's condition and functional level and to prevent relapse or hospitalization. When reference is made to an item or service qualifying for the partial hospitalization services benefit, this refers to provisions of the law which condition coverage upon the item or service meeting the definition of partial hospitalization services, that is, whether it meets the criteria of section 1861(ff).

#### V. RELEVANCE OF STATUTORY BASIS FOR DENIALS

Where either section 1861(ff) or section 1835(a)(2)(F) of the Act is the statutory basis for denial of a partial hospitalization services claim, limitation on liability

under section 1879 of the Act is not applicable and such denied partial hospitalization services claims cannot be paid under limitation on liability, nor can providers or beneficiaries either be protected or be held liable under limitation on liability, because such partial hospitalization services "technical denials" are statutory coverage denials.

An intermediary can deny partial hospitalization services which are not "reasonable and necessary for the diagnosis or active treatment of the individual's condition, reasonably expected to improve or maintain the individual's condition and functional level and to prevent relapse or hospitalization" on the basis of medical necessity under section 1862(a)(1)(A) of the Act, but only when the item or service cannot be denied under either section 1861( ff ) or section 1835(a)(2)(F). In these "medical necessity" denials, limitation on liability under section 1879 of the Act is applicable and such denied partial hospitalization services claims can be paid under limitation on liability, if all the elements are satisfied. Likewise, providers or beneficiaries may either be protected or be held liable under limitation on liability in such denials.

Therefore, the precise statutory basis for the coverage or denial of partial hospitalization services is crucial and determinative as to whether or not limitation on liability protections can be applied.

## VI. APPEAL RIGHTS

Providers have no appeal rights with respect to partial hospitalization services denials under either section 1861(ff) or section 1835(a)(2)(F) of the Act. Providers do have appeal rights with respect to partial hospitalization services denials under section 1862(a)(1)(A) of the Act.

There are no explicit statutory limitation on liability protections for beneficiaries in the case of partial hospitalization services "technical denials" under section 1861(ff) or denials for failure to meet the certification requirements of section 1835(a)(2)(F) of the Act. Usually, this means that the provider is free to bill the beneficiary for any such denied items and services. However, beneficiaries may have some other protections. If there are issues of fraud and abuse, the provisions of sections 1128, 1128A, and/or 1128B of the Act may provide certain protections to the beneficiaries. In addition, beneficiaries may have protection under various State statutes.

VII. EFFECTIVE DATE

This Ruling is effective February 10, 1997.

Dated: 2/10/97

Bruce C. Vladeck  
Bruce C. Vladeck  
Administrator,  
Health Care Financing  
Administration

**How to use these separators**

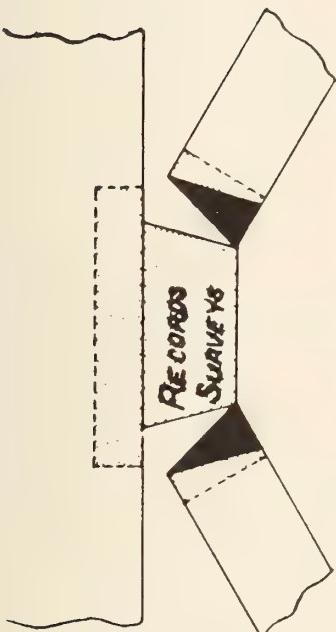
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# **HCFA Rulings**

**Department of Health  
and Human Services**

**Health Care Financing  
Administration**

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Ruling No 96-3

Date December 1996

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**HCFA Rulings** are binding on all HCFA components, Medicare contractors, the Provider Reimbursement Review Board, the Medicare Geographic Classification Review Board, the Departmental Appeals Board, and Administrative Law Judges who hear Medicare appeals. These decisions promote consistency in interpretation of policy and adjudication of disputes.

This Ruling states the existing policy of the Health Care Financing Administration concerning the requirements for determining if Medicare payment will be made under the limitation on liability provision, section 1879 of the Social Security Act, to a provider, practitioner, or other supplier for parenteral and enteral nutrition therapy, including intradialytic parenteral nutrition therapy, services and items for which Medicare payment is denied. This Ruling supplements HCFA Ruling 95-1 with respect to section 1879(g) of the Act.



**MEDICARE PROGRAM**

Hospital Insurance (Part A) and Supplementary Medical Insurance (Part B)

REQUIREMENTS FOR DETERMINING LIMITATION ON LIABILITY OF A MEDICARE BENEFICIARY, PROVIDER, PRACTITIONER, OR OTHER SUPPLIER FOR PARENTERAL AND ENTERAL NUTRITION THERAPY, INCLUDING INTRADIALYTIC PARENTERAL NUTRITION THERAPY, SERVICES AND ITEMS FOR WHICH MEDICARE PAYMENT IS DENIED.

**PURPOSE:** This Ruling states the existing policy of the Health Care Financing Administration concerning the requirements for determining if Medicare payment will be made under the limitation on liability provision, section 1879 of the Social Security Act, to a provider, practitioner, or other supplier for parenteral and enteral nutrition therapy, including intradialytic parenteral nutrition therapy, services and items for which Medicare payment is denied.

More specifically, this Ruling states the policy that any claims for intradialytic parenteral nutrition therapy, or any form of parenteral and enteral nutrition therapy, from a Medicare beneficiary who does not qualify for the prosthetic device benefit must be denied under section 1861(s)(8) of the Act. Medicare payment under limitation on liability

HCFAR 96-3-2

cannot be made for any parenteral and enteral nutrition therapy, including intradialytic parenteral nutrition therapy, denials which are based on section 1861(s)(8).

This Ruling supplements HCFA Ruling 95-1 with respect to section 1879(g) of the Act. The sunset date of December 31, 1995 for that provision is erroneous; section 1879(g) of the Act does not sunset.

**CITATIONS:** Sections 1142, 1154, 1814, 1815, 1833, 1834, 1861, 1862, 1866, and 1879 of the Social Security Act (42 U.S.C. 1320b-12, 1320c, 1395f, 1395g, 1395l, 1395m, 1395x, 1395y, 1395cc, and 1395pp), 42 CFR 411.400, 411.402, 411.404, 411.406, and HCFAR 95-1.

**RULING APPLICABLE TO DETERMINING LIMITATION ON LIABILITY OF A MEDICARE BENEFICIARY, PROVIDER, PRACTITIONER, OR OTHER SUPPLIER FOR PARENTERAL AND ENTERAL NUTRITION THERAPY, INCLUDING INTRADIALYTIC PARENTERAL NUTRITION THERAPY, SERVICES AND ITEMS FOR WHICH MEDICARE PAYMENT IS DENIED**

**I. BACKGROUND**

Section 1879 of the Social Security Act (the Act) provides financial relief to beneficiaries, providers, practitioners, and other suppliers by permitting Medicare payment to be made, or requiring refunds to be made, for certain services and items for which Medicare payment would

otherwise be denied. We refer to this section of the Act as "the limitation on liability provision."

The purpose of this Ruling is to provide a detailed clarification of our policy with regard to the limitation on liability provision as it applies to parenteral and enteral nutrition therapy, including intradialytic parenteral nutrition therapy, services and items to ensure that Medicare payment under the policy is made in an appropriate and consistent manner. This Ruling supplements HCFA Ruling 95-1 with respect to section 1879(g) of the Act.

**II. COVERAGE DENIALS TO WHICH THE LIMITATION ON LIABILITY PROVISION APPLIES - STATUTORY BASES**

A coverage determination for an item or service must be made before there can be a decision with respect to whether Medicare payment may be made under the limitation on liability provision. Medical review entities, acting for the Secretary, are authorized to make the coverage determinations. These entities include fiscal intermediaries, carriers, and Utilization and Quality Control Peer Review Organizations (PROs). In this Ruling, we refer to these entities collectively as Medicare contractors. These entities must act in accordance with the Medicare statutes, regulations, national coverage instructions, accepted standards of medical practice, and HCFA Rulings when making coverage determinations.

The claims payment and beneficiary indemnification provisions (sections 1879(a) and (b)) of the limitation on liability provision are applicable only to claims for beneficiary items or services submitted by providers, or by practitioners and other suppliers that have taken assignment, and only to claims for services, not otherwise statutorily excluded, that are denied on the basis of section 1862(a)(1), 1862(a)(9), 1879(e), or 1879(g) of the Act, which, under current law, include the following:

- Services and items found to be not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member (section 1862(a)(1)(A) of the Act).
- Pneumococcal vaccine and its administration, influenza vaccine and its administration, and hepatitis B vaccine and its administration, furnished to an individual at high or intermediate risk of contracting hepatitis B, that are not reasonable and necessary for the prevention of illness (section 1862(a)(1)(B) of the Act).
- Services and items which, in the case of hospice care, are not reasonable and necessary for the palliation or management of terminal illness (section 1862(a)(1)(C) of the Act).
- Clinical care services and items furnished with the concurrence of the Secretary and, with respect to research and experimentation conducted by, or under contract with,

the Prospective Payment Assessment Commission or the Secretary, that are not reasonable and necessary to carry out the purposes of section 1886(e)(6) of the Act (which concerns identification of medically appropriate patterns of health resources use) (section 1862(a)(1)(D) of the Act).

- Services and items that, in the case of research conducted pursuant to section 1142 of the Act, are not reasonable and necessary to carry out the purposes of that section (which concerns research on outcomes of health care services and procedures) (section 1862(a)(1)(E) of the Act).

- Screening mammography that is performed more frequently than is covered under section 1834(c)(2) of the Act or that is not conducted by a facility described in section 1834(c)(1)(B) of the Act and screening pap smears performed more frequently than is provided for under section 1861(nn) of the Act (section 1862(a)(1)(F) of the Act).

- Custodial care (section 1862(a)(9) of the Act).
- Inpatient hospital services or extended care services if payment is denied solely because of an unintentional, inadvertent, or erroneous action that resulted in the beneficiary's transfer from a certified bed (one that does not meet the requirements of section 1861(e) or (j) of the Act) in a skilled nursing facility (SNF) or hospital (section 1879(e) of the Act).

- Home health services determined to be noncovered because the beneficiary was not "homebound" or did not

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require "intermittent" skilled nursing care (as required by sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act) on or after July 1, 1987 (section 1879(g) of the Act). (The sunset date of December 31, 1995 for this provision, shown in HCFA Ruling 95-1, is erroneous; section 1879(g) of the Act does not sunset.)

Section 1879(h) of the Act provides for refunds by the supplier to the beneficiary in the case of certain claims for medical equipment and supplies, as they are defined in section 1834(j)(5) of the Act and including the prosthetic devices defined in section 1861(s)(8) of the Act, which are furnished on an assignment-related basis, and for which payment is denied. This Ruling deals primarily with section 1879(a) through (g), whereby Medicare payment may be made, or the beneficiary may be indemnified, under certain circumstances.

The refund provision (section 1879(h)) of the limitation on liability provision is applicable only to claims for beneficiary items or services which are furnished on an assignment-related basis by suppliers of medical equipment and supplies, and only to claims for medical equipment and supplies as defined in section 1834(j)(5) of the Act that are not otherwise statutorily excluded, that are denied on the basis of section 1834(j)(1), 1834(a)(15), or 1834(a)(17)(B) of the Act, which, under current law, include the following:

- Services and items for which no payment may be made by reason of the failure of the supplier to meet the supplier number requirements (section 1834(j)(1) of the Act).
- Services and items for which payment is denied in advance, with respect to services listed as potentially overutilized for which no prior authorization was obtained (section 1834(a)(15) of the Act).
- Services and items for which no payment may be made by reason of the prohibition on unsolicited telephone contacts (section 1834(a)(17)(B) of the Act).

**III. DENIALS FOR WHICH THE LIMITATION ON LIABILITY PROVISION DOES NOT APPLY**

Medicare payment under the limitation on liability provision cannot be made when Medicare coverage is denied on any basis other than one of the provisions of the law specified in section II. of this Ruling. There are certain claims, however, that may appear to involve a question of medical necessity, as described in section 1862(a)(1) of the Act, but the actual Medicare payment denial is based on a statutory provision other than section 1862(a)(1). Under these circumstances, Medicare payment under the limitation on liability provision cannot be made because the denial is not based on one of the statutory provisions specified in section II. of this Ruling.

A particular situation in which protection under the limitation on liability provision cannot be afforded is if parenteral and enteral nutrition therapy items and services, including intradialytic parenteral nutrition therapy items and services, are denied under section 1861(s)(8) of the Act. Medicare coverage of parenteral and enteral nutrition therapy is contained in section 1861(s)(8), the prosthetic device benefit, which provides that: "The term 'medical and other health services' means any of the following items or services: . . .(8) prosthetic devices (other than dental) which replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care), including replacement of such devices, and including one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens . . . ." Intradialytic parenteral nutrition therapy is a form of parenteral nutrition. Medicare coverage policies which apply to parenteral and enteral nutrition therapy items and services apply identically to intradialytic parenteral nutrition therapy items and services, because intradialytic parenteral nutrition therapy is a subset of parenteral and enteral nutrition therapy.

Coverage of parenteral and enteral nutrition therapy is amplified in Medicare Coverage Issues Manual section 65-10. Daily parenteral therapy is "considered reasonable and

necessary for a patient with severe pathology of the alimentary tract which does not allow absorption of sufficient nutrients to maintain weight and strength commensurate with the patient's general condition."

(Section 65-10.1.) Intradialytic parenteral nutrition therapy is administered to end stage renal disease (ESRD) patients while they are receiving dialysis. ESRD patients typically require hemodialysis three times per week for about three hours. These patients sometimes undergo parenteral therapy to replace fluids and nutrients lost during dialysis (Medicare Carriers Manual section 3329.5). ESRD patients must meet all of the parenteral nutrition therapy coverage requirements to receive intradialytic parenteral nutrition therapy. Those patients who do not meet all of the parenteral nutrition therapy coverage requirements are ineligible to receive Medicare coverage of intradialytic parenteral nutrition therapy under the prosthetic device benefit, and the statutory basis for the denial of any such claim for payment is section 1861(s)(8).

Any claims for intradialytic parenteral nutrition therapy, or for any form of parenteral and enteral nutrition therapy, from a Medicare beneficiary who does not qualify for the prosthetic device benefit must be denied under section 1861(s)(8). Medicare payment under limitation on liability cannot be made for any parenteral and enteral nutrition therapy, including intradialytic parenteral

**nutrition therapy, denials which are based on section 1861(s)(8).**

However, parenteral and enteral nutrition therapy, including intradialytic parenteral nutrition therapy, services and items which are otherwise covered under section 1861(s)(8) can be denied under section 1862(a)(1) for lack of medical necessity, in which case the protection under the limitation on liability provision can be afforded if all the elements are satisfied. The Medicare beneficiary must qualify for the prosthetic device benefit in order for any services or items to be otherwise covered under section 1861(s)(8).

Example: If a Medicare beneficiary with ESRD, a dialysis patient who meets all of the requirements for coverage of parenteral nutrition therapy, receives intradialytic parenteral nutrition therapy during dialysis and also receives parenteral nutrition therapy on other days of the week when the patient is not on dialysis, it may be determined that the patient is receiving an excessive number of lipids. A claim for Medicare payment which is denied because the patient, who qualifies for parenteral nutrition therapy coverage, is receiving an excessive number of lipids would be denied as not reasonable and necessary under section 1862(a)(1)(A) of the Act.

and the limitation on liability provision, section 1879 of the Act, would be applicable to that denial.

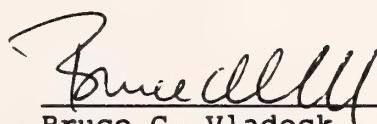
Therefore, the precise statutory basis for the coverage or denial of parenteral and enteral nutrition therapy, including intradialytic parenteral nutrition therapy, services and items is crucial and determinative as to whether or not limitation on liability protections can be applied.

Providers have no appeal rights with respect to parenteral and enteral nutrition therapy, including intradialytic parenteral nutrition therapy, denials under section 1861(s)(8) of the Act.

#### IV. EFFECTIVE DATE

This Ruling is effective December 12, 1996.

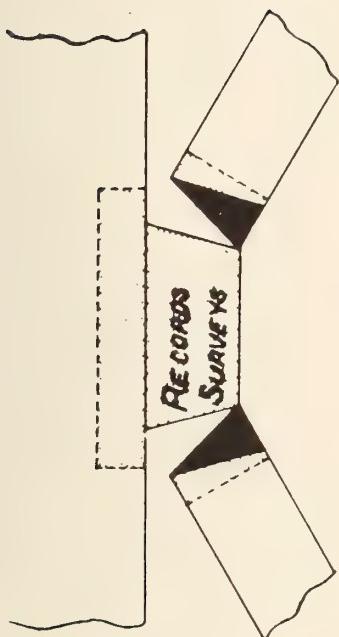
Dated: 12/12/96

  
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Bruce C. Vladeck  
Administrator,  
Health Care Financing  
Administration



**How to use these separators**

Look for your reference letter. The far left column designated "TAB" will indicate proper tab position for that number or letter. Cut off and discard all tabs except the one you wish to retain. Example: Position number "10" would be found behind the fourth tab. Position letter "C" would be found behind the third tab.



**TAB** (CHOOSE YOUR TAB)

FIRST	V	O	H	A
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THIRD	X	Q	J	C
FOURTH	Y	R	K	D
FIFTH	Z	S	L	E
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FOURTH		94	87	80	73	66	59	52	45	38	31	24	17	10	3
FIFTH		95	88	81	74	67	60	53	46	39	32	25	18	11	4
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SEVENTH		97	90	83	76	69	62	55	48	41	34	27	20	13	6



# **HCFA Rulings**

**Department of Health  
and Human Services**

**Health Care Financing  
Administration**

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Ruling No 96-2

Date November 1996

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**HCFA Rulings** are decisions of the Administrator that serve as precedent final opinions and orders and statements of policy and interpretation. They provide clarification and interpretation of complex or ambiguous statutory or regulatory provisions relating to Medicare, Medicaid, Utilization and Quality Control Peer Review, and related matters.

**HCFA Rulings** are binding on all HCFA components, Medicare contractors, the Office of Hearings, the Medicare Geographic Classification Review Board, the Departmental Appeals Board and Administrative Law Judges who hear Medicare appeals. These decisions promote consistency in interpretation of policy and adjudication of disputes.

This Ruling states the policy of the Health Care Financing Administration concerning the requirements for determining if Medicare payment will be made under the limitation on liability provision, section 1879 of the Social Security Act, to a supplier, practitioner, or other supplier for pap smears and mammography services for which Medicare payment is denied.



**MEDICARE PROGRAM**

Hospital Insurance (Part A) and Supplementary Medical Insurance (Part B)

**REQUIREMENTS FOR DETERMINING LIMITATION ON LIABILITY OF A MEDICARE BENEFICIARY, SUPPLIER, PRACTITIONER, OR OTHER SUPPLIER FOR PAP SMEARS AND MAMMOGRAPHY SERVICES FOR WHICH MEDICARE PAYMENT IS DENIED.**

**PURPOSE:** This Ruling states the policy of the Health Care Financing Administration concerning the requirements for determining if Medicare payment will be made under the limitation on liability provision, section 1879 of the Social Security Act, to a supplier, practitioner, or other supplier for pap smears and mammography services for which Medicare payment is denied.

**CITATIONS:** Sections 1142, 1154, 1814, 1815, 1833, 1834, 1842, 1861, 1862, 1866, and 1879 of the Social Security Act (42 U.S.C. 1320b-12, 1320c, 1395f, 1395g, 1395l, 1395m, 1395u, 1395x, 1395y, 1395cc, and 1395pp), 42 CFR 411.400, 411.402, 411.404, 411.406, and HCFAR 95-1.

RULING APPLICABLE TO DETERMINING LIMITATION ON LIABILITY OF  
A MEDICARE BENEFICIARY, SUPPLIER, PRACTITIONER, OR OTHER  
SUPPLIER FOR PAP SMEARS AND MAMMOGRAPHY SERVICES FOR WHICH  
MEDICARE PAYMENT IS DENIED

**I. BACKGROUND**

Section 1879 of the Social Security Act (the Act) provides financial relief to beneficiaries, suppliers, practitioners, and other suppliers by permitting Medicare payment to be made, or requiring refunds to be made, for certain services and items for which Medicare payment would otherwise be denied. We refer to this section of the Act as "the limitation on liability provision."

The purpose of this Ruling is to provide a detailed clarification of our policy with regard to the limitation on liability provision as it applies to pap smears and mammography services to ensure that Medicare payment under the policy is made in an appropriate and consistent manner. This Ruling supplements and extends HCFA Ruling 95-1.

**II. COVERAGE DENIALS TO WHICH THE LIMITATION ON LIABILITY PROVISION APPLIES - STATUTORY BASES**

A coverage determination for an item or service must be made before there can be a decision with respect to whether Medicare payment may be made under the limitation on liability provision. Medical review entities, acting for the Secretary, are authorized to make the coverage determinations. These entities include fiscal

intermediaries, carriers, and Utilization and Quality Control Peer Review Organizations. In this Ruling, we refer to these entities collectively as Medicare contractors. These entities must act in accordance with the Medicare statutes, regulations, national coverage instructions, accepted standards of medical practice, and HCFA Rulings when making coverage determinations.

The claims payment and beneficiary indemnification provisions (sections 1879(a) and (b)) of the limitation on liability provision are applicable only to claims for beneficiary items or services submitted by providers, or by practitioners and other suppliers that have taken assignment. These provisions are applicable only to claims for services, not otherwise statutorily excluded, that are denied on the basis of section 1862(a)(1), 1862(a)(9), 1879(e), or 1879(g) of the Act. Under current law, section 1862(a)(1) includes, in section 1862(a)(1)(F), screening mammography that is performed more frequently than is covered under section 1834(c)(2) or that is not conducted by a facility described in section 1834(c)(1)(B) and screening pap smears performed more frequently than is provided for under section 1861(nn).

Screening (as distinguished from diagnostic) mammography is defined in section 1861(jj); the frequency criterion for coverage is a provision of section 1834(c)(2); and the proper facility criterion is a provision of

section 1834(c)(1)(B). Screening pap smears are defined in section 1861(nn) and the frequency criterion for coverage is part of that definition. Nonetheless, the statutory basis of denial for screening mammography services which exceed the frequency criterion and/or fail the proper facility criterion, and for screening pap smears which exceed the frequency criterion, is section 1862(a)(1)(F) and, accordingly, limitation on liability under section 1879 applies to all such denials.

Section 1862(a)(1)(F) does not apply to diagnostic mammography claims. Limitation on liability under section 1879 applies to claims for diagnostic mammography services, if submitted under an assignment of benefits and denied under section 1862(a)(1)(A) as not reasonable and necessary.

If a screening mammogram is furnished to a beneficiary erroneously, that is, if the ordering physician, in fact, intended that a diagnostic mammogram be furnished, the statutory basis of denial depends upon the circumstances of the case. If the screening mammogram can be denied for failing the frequency criterion for coverage under section 1834(c)(2) and/or the proper facility criterion under section 1834(c)(1)(B), the claim must be denied on the basis of section 1862(a)(1)(F). If the claim cannot be denied on the basis of section 1862(a)(1)(F), the claim must be denied on the basis of section 1862(a)(1)(A) as not reasonable and necessary. Limitation on liability under section 1879 would

apply to any denial under either section 1862(a)(1)(F) or section 1862(a)(1)(A). In any such instance of an erroneously furnished screening mammogram, a beneficiary cannot be held liable by virtue of the provision to the beneficiary of an advance written notice of noncoverage, since the supplier/mammography center erred in providing a screening mammogram in the first place, a fact of which the beneficiary would have to be aware in order to be able to actually make an informed consumer decision to receive the screening mammogram. In all such instances of erroneously furnished screening mammograms, the supplier/mammography center is liable under section 1879 because it is expected to know that an order from a physician for a mammography service must specifically prescribe either a screening or diagnostic mammogram is to be performed, and that furnishing a screening mammogram when a diagnostic mammogram is prescribed is not covered by reason of section 1862(a)(1)(A), even if it otherwise could be covered under section 1862(a)(1)(F).

While this Ruling deals primarily with assignment-related claims and section 1879, whereby Medicare payment may be made or the beneficiary may be indemnified under certain circumstances, the following policy is noteworthy. For unassigned claims, the relevant liability protection issue is the applicability of the refund requirements of section 1842(l) which apply only to

physicians' services. Section 1848(j)(3) defines "physicians' services" for the purposes of section 1848, "Payment for Physicians' Services." Section 1848(j)(3) provides that the diagnostic x-ray tests, including diagnostic mammography, described in section 1861(s)(3), are physicians' services.

Therefore, because diagnostic mammography services are considered physicians' services, the refund requirements of section 1842(1) apply to claims for diagnostic mammography services submitted on an unassigned basis and denied under section 1862(a)(1)(A) as not reasonable and necessary. The physician or supplier/mammography center which furnishes a diagnostic mammography service may be required to make refund under section 1842(1). Where the service was ordered, but was not furnished, by an attending physician, the ordering physician cannot be required to make refund. Screening mammography is defined in section 1861(jj), not in section 1861(s)(3), and, therefore, is not a physicians' service. Because screening mammography is not considered a physicians' service, however, the refund requirements of section 1842(1) do not apply to claims for screening mammography services submitted on an unassigned basis and denied as not reasonable and necessary. Furthermore, limitation on liability under section 1879 cannot be applied to such denied unassigned claims for screening mammography services on the basis of a denial under either section

1862(a)(1)(A) or section 1862(a)(1)(F), because the claims are unassigned.

Virtually all pap smears (both technical and professional components) are clinical diagnostic laboratory tests. Assignment is taken on all such pap smears, whether furnished under the diagnostic pap smear benefit or the screening pap smear benefit, because all clinical diagnostic laboratory tests must be assigned. Therefore, section 1842(l) is never applied to any such pap smear denials. Section 1879 may be applied to denials under section 1862(a)(1)(F) of screening pap smears which exceed the frequency criterion in section 1861(nn), and to denials of any pap smear (whether diagnostic or screening) found to be not reasonable and necessary under section 1862(a)(1)(A).

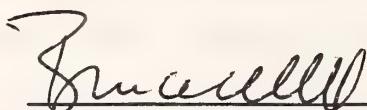
Solely in the case of a pap smear (diagnostic or screening) furnished to a hospital inpatient, if the physician bills for the professional component (e.g., interpretation) of the test as a physicians' service, that claim may be submitted on an unassigned basis; in which case, limitation on liability under section 1879 cannot be applied to denials of any such unassigned claims, but section 1842(l) may apply if the claim is denied under section 1862(a)(1).

HCFAR 96-2-8

III. EFFECTIVE DATE

This Ruling is effective November 6, 1996, 1996.

Dated: November 6, 1996

  
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Bruce C. Vladeck  
Administrator,  
Health Care Financing  
Administration



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**HEALTH & HUMAN SERVICES**  
HEALTH CARE FINANCING ADMINISTRATION  
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**OFFICIAL BUSINESS**

# **HCFA Rulings**

**Department of Health  
and Human Services**

**Health Care Financing  
Administration**

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Ruling No 96-2

Date November 1996

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**REQUIREMENTS FOR DETERMINING LIMITATION ON LIABILITY OF A MEDICARE BENEFICIARY, SUPPLIER, PRACTITIONER, OR OTHER SUPPLIER FOR PAP SMEARS AND MAMMOGRAPHY SERVICES FOR WHICH MEDICARE PAYMENT IS DENIED.**

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Section 1862(a)(1)(F) does not apply to diagnostic mammography claims. Limitation on liability under section 1879 applies to claims for diagnostic mammography services, if submitted under an assignment of benefits and denied under section 1862(a)(1)(A) as not reasonable and necessary.

If a screening mammogram is furnished to a beneficiary erroneously, that is, if the ordering physician, in fact, intended that a diagnostic mammogram be furnished, the statutory basis of denial depends upon the circumstances of the case. If the screening mammogram can be denied for failing the frequency criterion for coverage under section 1834(c)(2) and/or the proper facility criterion under section 1834(c)(1)(B), the claim must be denied on the basis of section 1862(a)(1)(F). If the claim cannot be denied on the basis of section 1862(a)(1)(F), the claim must be denied on the basis of section 1862(a)(1)(A) as not reasonable and necessary. Limitation on liability under section 1879 would

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While this Ruling deals primarily with assignment-related claims and section 1879, whereby Medicare payment may be made or the beneficiary may be indemnified under certain circumstances, the following policy is noteworthy. For unassigned claims, the relevant liability protection issue is the applicability of the refund requirements of section 1842(l) which apply only to

physicians' services. Section 1848(j)(3) defines "physicians' services" for the purposes of section 1848, "Payment for Physicians' Services." Section 1848(j)(3) provides that the diagnostic x-ray tests, including diagnostic mammography, described in section 1861(s)(3), are physicians' services.

Therefore, because diagnostic mammography services are considered physicians' services, the refund requirements of section 1842(l) apply to claims for diagnostic mammography services submitted on an unassigned basis and denied under section 1862(a)(1)(A) as not reasonable and necessary. The physician or supplier/mammography center which furnishes a diagnostic mammography service may be required to make refund under section 1842(l). Where the service was ordered, but was not furnished, by an attending physician, the ordering physician cannot be required to make refund. Screening mammography is defined in section 1861(jj), not in section 1861(s)(3), and, therefore, is not a physicians' service. Because screening mammography is not considered a physicians' service, however, the refund requirements of section 1842(l) do not apply to claims for screening mammography services submitted on an unassigned basis and denied as not reasonable and necessary. Furthermore, limitation on liability under section 1879 cannot be applied to such denied unassigned claims for screening mammography services on the basis of a denial under either section

1862(a)(1)(A) or section 1862(a)(1)(F), because the claims are unassigned.

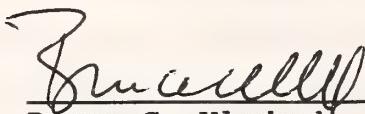
Virtually all pap smears (both technical and professional components) are clinical diagnostic laboratory tests. Assignment is taken on all such pap smears, whether furnished under the diagnostic pap smear benefit or the screening pap smear benefit, because all clinical diagnostic laboratory tests must be assigned. Therefore, section 1842(1) is never applied to any such pap smear denials. Section 1879 may be applied to denials under section 1862(a)(1)(F) of screening pap smears which exceed the frequency criterion in section 1861(nn), and to denials of any pap smear (whether diagnostic or screening) found to be not reasonable and necessary under section 1862(a)(1)(A).

Solely in the case of a pap smear (diagnostic or screening) furnished to a hospital inpatient, if the physician bills for the professional component (e.g., interpretation) of the test as a physicians' service, that claim may be submitted on an unassigned basis; in which case, limitation on liability under section 1879 cannot be applied to denials of any such unassigned claims, but section 1842(1) may apply if the claim is denied under section 1862(a)(1).

**III. EFFECTIVE DATE**

This Ruling is effective November 6, 1996, 1996.

Dated: November 6, 1996



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Bruce C. Vladeck  
Administrator,  
Health Care Financing  
Administration



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## HCFA Rulings

Department of Health  
and Human Services

Health Care Financing  
Administration

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Ruling No 96-2

Date November 1996

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**HCFA Rulings** are decisions of the Administrator that serve as precedent final opinions and orders and statements of policy and interpretation. They provide clarification and interpretation of complex or ambiguous statutory or regulatory provisions relating to Medicare, Medicaid, Utilization and Quality Control Peer Review, and related matters.

HCFA Rulings are binding on all HCFA components, Medicare contractors, the Office of Hearings, the Medicare Geographic Classification Review Board, the Departmental Appeals Board and Administrative Law Judges who hear Medicare appeals. These decisions promote consistency in interpretation of policy and adjudication of disputes.

This Ruling states the policy of the Health Care Financing Administration concerning the requirements for determining if Medicare payment will be made under the limitation on liability provision, section 1879 of the Social Security Act, to a supplier, practitioner, or other supplier for pap smears and mammography services for which Medicare payment is denied.



**MEDICARE PROGRAM**

**Hospital Insurance (Part A) and Supplementary Medical Insurance (Part B)**

**REQUIREMENTS FOR DETERMINING LIMITATION ON LIABILITY OF A MEDICARE BENEFICIARY, SUPPLIER, PRACTITIONER, OR OTHER SUPPLIER FOR PAP SMEARS AND MAMMOGRAPHY SERVICES FOR WHICH MEDICARE PAYMENT IS DENIED.**

**PURPOSE:** This Ruling states the policy of the Health Care Financing Administration concerning the requirements for determining if Medicare payment will be made under the limitation on liability provision, section 1879 of the Social Security Act, to a supplier, practitioner, or other supplier for pap smears and mammography services for which Medicare payment is denied.

**CITATIONS:** Sections 1142, 1154, 1814, 1815, 1833, 1834, 1842, 1861, 1862, 1866, and 1879 of the Social Security Act (42 U.S.C. 1320b-12, 1320c, 1395f, 1395g, 1395l, 1395m, 1395u, 1395x, 1395y, 1395cc, and 1395pp), 42 CFR 411.400, 411.402, 411.404, 411.406, and HCFAR 95-1.

**RULING APPLICABLE TO DETERMINING LIMITATION ON LIABILITY OF  
A MEDICARE BENEFICIARY, SUPPLIER, PRACTITIONER, OR OTHER  
SUPPLIER FOR PAP SMEARS AND MAMMOGRAPHY SERVICES FOR WHICH  
MEDICARE PAYMENT IS DENIED**

**I. BACKGROUND**

Section 1879 of the Social Security Act (the Act) provides financial relief to beneficiaries, suppliers, practitioners, and other suppliers by permitting Medicare payment to be made, or requiring refunds to be made, for certain services and items for which Medicare payment would otherwise be denied. We refer to this section of the Act as "the limitation on liability provision."

The purpose of this Ruling is to provide a detailed clarification of our policy with regard to the limitation on liability provision as it applies to pap smears and mammography services to ensure that Medicare payment under the policy is made in an appropriate and consistent manner. This Ruling supplements and extends HCFA Ruling 95-1.

**II. COVERAGE DENIALS TO WHICH THE LIMITATION ON LIABILITY  
PROVISION APPLIES - STATUTORY BASES**

A coverage determination for an item or service must be made before there can be a decision with respect to whether Medicare payment may be made under the limitation on liability provision. Medical review entities, acting for the Secretary, are authorized to make the coverage determinations. These entities include fiscal

intermediaries, carriers, and Utilization and Quality Control Peer Review Organizations. In this Ruling, we refer to these entities collectively as Medicare contractors. These entities must act in accordance with the Medicare statutes, regulations, national coverage instructions, accepted standards of medical practice, and HCFA Rulings when making coverage determinations.

The claims payment and beneficiary indemnification provisions (sections 1879(a) and (b)) of the limitation on liability provision are applicable only to claims for beneficiary items or services submitted by providers, or by practitioners and other suppliers that have taken assignment. These provisions are applicable only to claims for services, not otherwise statutorily excluded, that are denied on the basis of section 1862(a)(1), 1862(a)(9), 1879(e), or 1879(g) of the Act. Under current law, section 1862(a)(1) includes, in section 1862(a)(1)(F), screening mammography that is performed more frequently than is covered under section 1834(c)(2) or that is not conducted by a facility described in section 1834(c)(1)(B) and screening pap smears performed more frequently than is provided for under section 1861(nn).

Screening (as distinguished from diagnostic) mammography is defined in section 1861(jj); the frequency criterion for coverage is a provision of section 1834(c)(2); and the proper facility criterion is a provision of

section 1834(c)(1)(B). Screening pap smears are defined in section 1861(nn) and the frequency criterion for coverage is part of that definition. Nonetheless, the statutory basis of denial for screening mammography services which exceed the frequency criterion and/or fail the proper facility criterion, and for screening pap smears which exceed the frequency criterion, is section 1862(a)(1)(F) and, accordingly, limitation on liability under section 1879 applies to all such denials.

Section 1862(a)(1)(F) does not apply to diagnostic mammography claims. Limitation on liability under section 1879 applies to claims for diagnostic mammography services, if submitted under an assignment of benefits and denied under section 1862(a)(1)(A) as not reasonable and necessary.

If a screening mammogram is furnished to a beneficiary erroneously, that is, if the ordering physician, in fact, intended that a diagnostic mammogram be furnished, the statutory basis of denial depends upon the circumstances of the case. If the screening mammogram can be denied for failing the frequency criterion for coverage under section 1834(c)(2) and/or the proper facility criterion under section 1834(c)(1)(B), the claim must be denied on the basis of section 1862(a)(1)(F). If the claim cannot be denied on the basis of section 1862(a)(1)(F), the claim must be denied on the basis of section 1862(a)(1)(A) as not reasonable and necessary. Limitation on liability under section 1879 would

apply to any denial under either section 1862(a)(1)(F) or section 1862(a)(1)(A). In any such instance of an erroneously furnished screening mammogram, a beneficiary cannot be held liable by virtue of the provision to the beneficiary of an advance written notice of noncoverage, since the supplier/mammography center erred in providing a screening mammogram in the first place, a fact of which the beneficiary would have to be aware in order to be able to actually make an informed consumer decision to receive the screening mammogram. In all such instances of erroneously furnished screening mammograms, the supplier/mammography center is liable under section 1879 because it is expected to know that an order from a physician for a mammography service must specifically prescribe either a screening or diagnostic mammogram is to be performed, and that furnishing a screening mammogram when a diagnostic mammogram is prescribed is not covered by reason of section 1862(a)(1)(A), even if it otherwise could be covered under section 1862(a)(1)(F).

While this Ruling deals primarily with assignment-related claims and section 1879, whereby Medicare payment may be made or the beneficiary may be indemnified under certain circumstances, the following policy is noteworthy. For unassigned claims, the relevant liability protection issue is the applicability of the refund requirements of section 1842(l) which apply only to

physicians' services. Section 1848(j)(3) defines "physicians' services" for the purposes of section 1848, "Payment for Physicians' Services." Section 1848(j)(3) provides that the diagnostic x-ray tests, including diagnostic mammography, described in section 1861(s)(3), are physicians' services.

Therefore, because diagnostic mammography services are considered physicians' services, the refund requirements of section 1842(1) apply to claims for diagnostic mammography services submitted on an unassigned basis and denied under section 1862(a)(1)(A) as not reasonable and necessary. The physician or supplier/mammography center which furnishes a diagnostic mammography service may be required to make refund under section 1842(1). Where the service was ordered, but was not furnished, by an attending physician, the ordering physician cannot be required to make refund. Screening mammography is defined in section 1861(jj), not in section 1861(s)(3), and, therefore, is not a physicians' service. Because screening mammography is not considered a physicians' service, however, the refund requirements of section 1842(1) do not apply to claims for screening mammography services submitted on an unassigned basis and denied as not reasonable and necessary. Furthermore, limitation on liability under section 1879 cannot be applied to such denied unassigned claims for screening mammography services on the basis of a denial under either section

1862(a)(1)(A) or section 1862(a)(1)(F), because the claims are unassigned.

Virtually all pap smears (both technical and professional components) are clinical diagnostic laboratory tests. Assignment is taken on all such pap smears, whether furnished under the diagnostic pap smear benefit or the screening pap smear benefit, because all clinical diagnostic laboratory tests must be assigned. Therefore, section 1842(l) is never applied to any such pap smear denials. Section 1879 may be applied to denials under section 1862(a)(1)(F) of screening pap smears which exceed the frequency criterion in section 1861(nn), and to denials of any pap smear (whether diagnostic or screening) found to be not reasonable and necessary under section 1862(a)(1)(A).

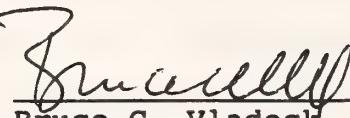
Solely in the case of a pap smear (diagnostic or screening) furnished to a hospital inpatient, if the physician bills for the professional component (e.g., interpretation) of the test as a physicians' service, that claim may be submitted on an unassigned basis; in which case, limitation on liability under section 1879 cannot be applied to denials of any such unassigned claims, but section 1842(l) may apply if the claim is denied under section 1862(a)(1).

HCFAR 96-2-8

**III. EFFECTIVE DATE**

This Ruling is effective November 6, 1996, 1996.

Dated: November 6, 1996

  
\_\_\_\_\_  
Bruce C. Vladeck  
Administrator,  
Health Care Financing  
Administration



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SIXTH		96	89	82	75	68	61	54	47	40	33	26	19	12	5
SEVENTH		97	90	83	76	69	62	55	48	41	34	27	20	13	6



# HCFA Rulings

Department of Health  
and Human Services

Health Care Financing  
Administration

Ruling No 96-1

Date September 1996

**HCFA Rulings** are decisions of the Administrator that serve as precedent final opinions and orders and statements of policy and interpretation. They provide clarification and interpretation of complex or ambiguous provisions of the law or regulations relating to Medicare, Medicaid, Utilization and Quality Control Peer Review, and related matters.

HCFA Rulings are binding on all HCFA components, its intermediaries and carriers, including carrier hearing officers, the Provider Reimbursement Review Board, the Medicare Geographic Classification Review Board, the Departmental Appeals Board, and administrative law judges who hear Medicare appeals. These Rulings promote consistency in interpretation of policy and adjudication of disputes.

This Ruling states the policy of the Health Care Financing Administration regarding the distinction between the statutory benefits of "orthotics" and "durable medical equipment" under Medicare Part B. The distinction may have an effect on the Medicare approved amount of payment and is necessary in those instances where items are furnished in

skilled nursing facilities that meet the definition in section 1819(a)(1) of the Social Security Act (the Act) or hospitals due to the express exclusion from Part B coverage of durable medical equipment when used in a hospital or skilled nursing facility.

The Ruling clarifies that the "orthotics" benefit in section 1861(s)(9) of the Act, insofar as braces are concerned, is limited to leg, arm, back, and neck braces that are used independently rather than in conjunction with, or as components of, other medical or non-medical equipment. It also clarifies that accessories used in conjunction with, and necessary for the full functioning of, durable medical equipment fall under the durable medical equipment benefits category. Finally, the Ruling provides several examples that illustrate the application and scope of these two terms.

**MEDICARE PROGRAM**

**Medicare Supplementary Medical Insurance (Part B)**

**CLARIFICATION OF THE TERMS "ORTHOPTICS," "BRACES," AND  
"DURABLE MEDICAL EQUIPMENT" UNDER MEDICARE PART B**

**HELD:** The "orthotics" benefit described in section 1861(s)(9) of the Social Security Act, insofar as braces are concerned, is limited to leg, arm, back, and neck braces that are used independently, rather than in conjunction with, or as components of, other medical or non-medical equipment. It is also held that leg, arm, back, and neck braces used in conjunction with, and necessary for the full functioning of, durable medical equipment are accessories to the durable medical equipment and, hence, subject to the requirements of section 1861(n) of the Social Security Act.

**CITATIONS:** Sections 1834(a)(4) and (h) and 1861(n) and (s)(9) of the Social Security Act (42 U.S.C. 1395m(a)(4) and (h) and 1395x(n) and (s)(9); and 42 CFR 414.202.

**BACKGROUND**

The Medicare program's long-standing policy has been to limit payment for "orthotics" under Medicare Part B to leg,

arm, back, and neck braces that are stand-alone devices used independently of other kinds of medical equipment. Recent decisions issued by administrative law judges and Medicare carrier hearing officers have, however, diverged from this policy and have interpreted section 1861(s)(9) of the Act, insofar as braces are concerned, as encompassing all devices that serve to support or restrict motion in a part of the body, even if the devices may not reasonably be used on their own and are primarily intended to be used with other equipment. The purpose of this Ruling is to provide clarification and guidance regarding the scope and meaning of the statutory benefits for "orthotics" and "durable medical equipment."

## ORTHOTICS

Section 1834(h) of the Social Security Act (the Act) provides for payment of "orthotics and prosthetics" as described "in section 1861(s)(9)[.]" Section 1861(s)(9) of the Act in turn lists only the following:

- (9) leg, arm, back, and neck braces, and artificial legs, arms, and eyes, including replacements if required because of a change in the patient's physical condition[.]

In light of this limited statutory language, we defined "orthotic devices" in 42 CFR 414.202 of our regulations, which states in pertinent part:

Prosthetic and orthotic devices means--

\* \* \* \* \*

(3) Leg, arm, back, and neck braces, and artificial legs, arms, and eyes, including replacements if required because of a change in the beneficiary's physical condition. (Emphasis added).

#### DURABLE MEDICAL EQUIPMENT

In contrast to the very specific wording of section 1861(s)(9) of the Act, section 1861(n) of the Act employs an open-ended reference to what constitutes "durable medical equipment" by stating that the term "includes" items, such as oxygen tents, hospital beds, and wheelchairs, that may be used in the home. Our definition of durable medical equipment set forth at 42 CFR 414.202, in part, tracks this language by referring in a similarly open-ended manner to medical equipment that can withstand repeated use and is appropriate for use in the home. In light of the breadth of the durable medical equipment category set forth in the statute and regulation, section 2100.5 of the Medicare Carrier's Manual, Part 3 - Claims Process, "Coverage of Supplies and Accessories," provides that

payment for durable medical equipment extends to coverage of "supplies and accessories" that are "necessary for the effective use of durable medical equipment."

#### SEATING DEVICES AS AN EXAMPLE OF DURABLE MEDICAL EQUIPMENT

Many items, including wheelchairs and hospital beds (both expressly classified as durable medical equipment under section 1861(n) of the Act and section 2100.1 of the Medicare Carrier's Manual, Part 3 - Claims Process, "Definition of Durable Medical Equipment"), support portions of the body. Other items, such as splints or casts (both classified under section 1861(s)(5) of the Act), protect or restrict movement of a portion of the body. None of these items is appropriately classified as a "brace" under section 1861(s)(9) of the Act. (We also generally exclude orthopedic shoes or other shoe inserts or supportive devices for the feet from coverage.)

To the extent that a wheelchair seating system or other equipment may or may not function properly or not achieve its full "therapeutic benefit" without attached components supporting or restricting motion in a body part, the attachments are appropriately viewed as a necessary accessory that is an integral part of the durable medical equipment and is, accordingly, payable as durable medical

equipment, provided that the other prerequisites for classification as durable medical equipment are met.

Many seating systems (including wheelchairs) incorporate as integral parts various rests and supporting and positional attachments that are modifications of the seating system and that are intended to be used with the seating system to which they are attached. Section 1861(n) of the Act expressly classifies wheelchairs as durable medical equipment. Furthermore, the legislative history and prior Congressional enactments evidence no intent to classify separately integral components or attachments to seating systems as "braces."

Section 4152(c)(4) of the Omnibus Budget Reconciliation Act of 1990 (OBRA 1990), Public Law 101-508, enacted on November 5, 1990, amended section 1834(a)(4) of the Act, governing customized durable medical equipment, to extend coverage to customized wheelchairs that have been "measured, fitted, or adapted in consideration" of a patient's "disability" and including "customized features, modifications, or components" in "accordance with instructions from the patient's physician." The Congress explained that these customized features could "include, but are not limited to" items such as "attachments to convert wheelchairs to one-armed drive," "postural control devices," and "custom molded cushions and inserts or lateral

supports." (House Report No. 101-881, 101st Cong., 2d Sess., 1990 USCCAN at 2270.) Thus, ample evidence establishes that the Congress intended sophisticated wheelchairs, including chairs with functional attachments, to be classified in their totality as durable medical equipment.

Even though the Congress was addressing customized wheelchairs, the intent to classify this equipment in its totality as durable medical equipment extends by analogy to ordinary wheelchairs with attachments. Taken together with the narrow wording of section 1861(s)(9) of the Act, the Congress's treatment of attachments to wheelchairs thus strongly supports the conclusion that a device supporting or restricting motion in a body part but that is an integral part of other equipment is not appropriately classified under the brace benefits category set forth in section 1861(s)(9) of the Act. Our long-standing policy governing the breadth of the durable medical equipment benefits category reflects this congressional intent.

#### **CONCLUSION AND ILLUSTRATIONS**

For the reasons set forth above, we therefore conclude that "orthotics" payable under section 1861(s)(9), insofar as braces are concerned, and sections 1834(a) and (h) of the Act are properly limited to leg, arm, back, and neck braces

that are stand-alone devices used independently of other kinds of medical equipment. When a device that supports or restricts motion in a part of the body is not generally used, or may not reasonably be used, on its own and is primarily intended to be used with other medical or non-medical equipment payable as durable medical equipment, the durable medical equipment benefits category, and not the brace benefits category, applies.

Following are three examples that illustrate the application and scope of the terms "orthotics" and "durable medical equipment":

Illustration 1. A supplier manufactures and supplies medical devices to individuals who are generally elderly and suffer from Alzheimer's or other debilitating neuromuscular diseases that have caused them to be nonambulatory, immobile, and confined to a chair or bed. Due to their immobility, these patients may suffer from secondary complications, such as pressure sores, multisited contractures, musculoskeletal degeneration and deformities, and circulatory problems.

Under a physician's order, the supplier furnishes individually fitted attachments designed to be used in conjunction with a chair to seat and position the patient. The attachments, which the supplier labels "orthotic braces," are alleged to position limbs and other body parts

properly; restrict motion or weight bearing; immobilize and protect weak musculoskeletal segments; reduce load; retard progression of musculoskeletal deformity; and improve function. The design of the supplier's "orthotic braces" requires them to be attached to the chair frame, and the "orthotic braces" cannot function or be used apart from the chair to which they are attached.

Discussion: Although the devices in question may support or restrict movement in parts of the body, they are not braces within the meaning of 1861(s)(9) of the Act because they are integral parts of a seating system and are not designed or intended to be used apart from the seating system.

Illustration 2. A supplier furnishes what it describes as a lumbar support cushion comprised of a number of attachment straps and front and back cushions molded to fit the patient's body. The device is alleged to supply corrective support and pressure to the back to address postural defects and conditions such as scoliosis (curvature of the spine). Although capable of being worn separately while standing or lying down, the device is designed to fit into a seated base. In practice, the device is also predominantly worn and used while the patient is seated and is most frequently used by patients who are largely chairbound.

Discussion: Although the device in question may support or restrict movement in parts of the body, it is primarily intended to be used in conjunction with a seat and is comparable to a custom molded cushion or seat insert. The support cushion is accordingly not a brace within the meaning of section 1861(s)(9) of the Act.

Illustration 3. A supplier manufactures a sophisticated hospital bed with motorized sections that may be individually adjusted to position the patient's body and with straps and lateral support devices that provide support and limit movement of the patient's extremities, including limbs. The bed, with its lateral supports, is used with patients who have suffered severe accident trauma, including potential spinal cord injury, and who must be carefully positioned with limited motion to prevent further injury.

Discussion: Although the lateral supports, straps, and motorized sections support and restrict motion in parts of the body, all of these features are integral parts of a hospital bed, which is classified as durable medical equipment, and these components may therefore not be separately categorized as braces under section 1861(s)(9) of the Act.

**HELD:** The "orthotics" benefit described in section 1861(s)(9), insofar as braces are concerned, and

HCFAR 96-1-10

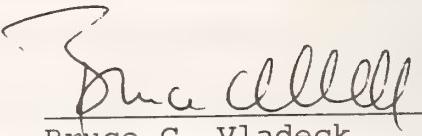
sections 1834(a) and (h) of the Social Security Act is limited to leg, arm, back, and neck braces that are used independently, rather than in conjunction with, or as components of, other medical or non-medical equipment. It is also held that leg, arm, back, and neck braces used in conjunction with, and necessary for the full functioning of, durable medical equipment are accessories to the durable medical equipment and, hence, subject to the requirements of section 1861(n) of the Social Security Act.

**EFFECTIVE DATE**

This Ruling is effective September 18, 1996.

Dated:

9/18/91

  
\_\_\_\_\_  
Bruce C. Vladick  
Administrator,  
Health Care Financing  
Administration

**How to use these separators**

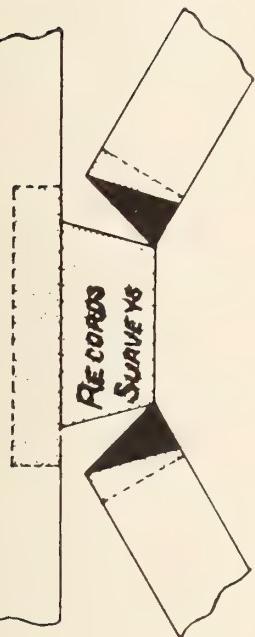
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# HCFA Rulings

Department of Health  
and Human Services

Health Care Financing  
Administration

Ruling No

95-1

Date December 1995

**HCFA Rulings** are decisions of the Administrator that serve as precedent final opinions and orders and statements of policy and interpretation. They provide clarification and interpretation of complex or ambiguous provisions of the law or regulations relating to Medicare, Medicaid, Utilization and Quality Control Peer Review, and related matters.

**HCFA Rulings** are binding on all HCFA components, the Provider Reimbursement Review Board, the Medicare Geographic Classification Review Board, the Appeals Council, and Administrative Law Judges who hear Medicare appeals. These Rulings promote consistency in interpretation of policy and adjudication of disputes.

This Ruling states the policy of the Health Care Financing Administration concerning the requirements for determining if Medicare payment will be made under the limitation on liability provisions, section 1879 of the Social Security Act, to a provider, practitioner, or other supplier for certain services and items for which Medicare payment is denied.



**MEDICARE PROGRAM**

**Hospital Insurance (Part A) and Supplementary Medical  
Insurance (Part B)**

**REQUIREMENTS FOR DETERMINING LIMITATION ON LIABILITY OF A  
MEDICARE BENEFICIARY, PROVIDER, PRACTITIONER, OR OTHER  
SUPPLIER FOR CERTAIN SERVICES AND ITEMS FOR WHICH MEDICARE  
PAYMENT IS DENIED.**

**PURPOSE:** This Ruling states the policy of the Health Care Financing Administration concerning the requirements for determining if Medicare payment will be made under the limitation on liability provision, section 1879 of the Social Security Act, to a provider, practitioner, or other supplier for certain services and items for which Medicare payment is denied.

**CITATIONS:** Sections 1142, 1154, 1814, 1815, 1833, 1834, 1861, 1862, 1866, and 1879 of the Social Security Act (42 USC 1320b-12, 1320c, 1395f, 1395g, 1395l, 1395m, 1395x, 1395y, 1395cc, and 1395pp) and 42 CFR 411.400, 411.402, 411.404 and 411.406.

RULING APPLICABLE TO DETERMINING LIMITATION ON LIABILITY OF  
A MEDICARE BENEFICIARY, PROVIDER, PRACTITIONER, OR OTHER  
SUPPLIER FOR CERTAIN SERVICES AND ITEMS FOR WHICH MEDICARE  
PAYMENT IS DENIED

I. BACKGROUND

Section 1879 of the Social Security Act (the Act) provides financial relief to beneficiaries, providers, practitioners, and other suppliers by permitting Medicare payment to be made, or requiring refunds to be made, for certain services and items for which Medicare payment would otherwise be denied. We refer to this section of the Act as "the limitation on liability provision."

The Medicare program currently pays out millions of dollars each year under the limitation on liability provision. The purpose of this Ruling is to provide a detailed clarification of our policy with regard to the limitation on liability provision to ensure that Medicare payment under the policy is made in an appropriate and consistent manner.

Medicare payment under the limitation on liability provision is dependent upon two primary factors. First, the claims for the services or items furnished must have been denied for one of the following reasons. The services or items were:

- not reasonable and necessary under section

1862(a)(1) of the Act;

- for custodial care and, therefore, not covered under section 1862(a)(9) of the Act;
- denied because the beneficiary was unintentionally, inadvertently, or erroneously placed into a noncertified bed (one that does not meet the requirements of section 1861(e) or (j) of the Act), as referenced by section 1879(e) of the Act; or
- noncovered home health services furnished to a beneficiary who was not "homebound" or who did not require "intermittent skilled nursing care" (as required by sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act), as referenced by section 1879(g) of the Act.

The second factor in determining if Medicare payment is made under the limitation on liability provision is whether the beneficiary and/or the provider, practitioner, or other supplier knew or could reasonably have been expected to know that the items or services (for which Medicare payment was denied on one of the bases listed above) were excluded from coverage. A determination of whether the protection under the limitation on liability provision can be afforded for a denied claim is made as a result of a prepayment medical review or a postpayment audit review.

Section 1879(h) of the Act provides for refunds by the supplier to the beneficiary in the case of certain claims for durable medical equipment (DME) for which payment is denied. This Ruling deals primarily with section 1879(a)

through (g), whereby Medicare payment may be made, or the beneficiary may be indemnified, under certain circumstances.

**II. COVERAGE DENIALS TO WHICH THE LIMITATION ON LIABILITY PROVISION APPLIES**

**A. Statutory Bases**

A coverage determination for an item or service must be made before there can be a decision with respect to whether Medicare payment may be made under the limitation on liability provision. Medical review entities, acting for the Secretary, are authorized to make the coverage determinations. These entities include fiscal intermediaries, carriers, and Utilization and Quality Control Peer Review Organizations (PROs). In this Ruling we refer to these entities collectively as Medicare contractors. These entities must act in accordance with the Medicare statutes, regulations, national coverage instructions, accepted standards of medical practice, and HCFA Rulings when making coverage determinations.

The claims payment and beneficiary indemnification provisions (sections 1879(a) and (b)) of the limitation on liability provision are applicable only to claims for beneficiary items or services submitted by providers, or by practitioners and other suppliers that have taken assignment, and only to claims for services, not otherwise statutorily excluded, that are denied on the basis of section 1862(a)(1), 1862(a)(9), 1879(e), or 1879(g) of the Act, which, under current law, include the following:

- Services and items found to be not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member (section 1862(a)(1)(A) of the Act).
- Pneumococcal vaccine and its administration, influenza vaccine and its administration, and hepatitis B vaccine and its administration, furnished to an individual at high or intermediate risk of contracting hepatitis B, that are not reasonable and necessary for the prevention of illness (section 1862(a)(1)(B) of the Act).
- Services and items which, in the case of hospice care, are not reasonable and necessary for the palliation or management of terminal illness (section 1862(a)(1)(C) of the Act).
- Clinical care services and items furnished with the concurrence of the Secretary and, with respect to research and experimentation conducted by, or under contract with, the Prospective Payment Assessment Commission or the Secretary, that are not reasonable and necessary to carry out the purposes of section 1886(e)(6) of the Act (which concerns identification of medically appropriate patterns of health resources use) (section 1862(a)(1)(D) of the Act).
- Services and items that, in the case of research conducted pursuant to section 1142 of the Act, are not reasonable and necessary to carry out the purposes of that section (which concerns research on outcomes of health care services and procedures) (section 1862(a)(1)(E) of the Act).

- Screening mammography that is performed more frequently than is covered under section 1834(c)(2) of the Act or that is not conducted by a facility described in section 1834(c)(1)(B) of the Act and screening pap smears performed more frequently than is provided for under section 1861(nn) of the Act (section 1862(a)(1)(F) of the Act).

- Custodial care (section 1862(a)(9) of the Act).
- Inpatient hospital services or extended care services if payment is denied solely because of an unintentional, inadvertent, or erroneous action that resulted in the beneficiary's transfer from a certified bed (one that does not meet the requirements of section 1861(e) or (j) of the Act) in a skilled nursing facility (SNF) or hospital (section 1879(e) of the Act).

- Home health services determined to be noncovered because the beneficiary was not "homebound" or did not require "intermittent" skilled nursing care (as required by sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act) on or after July 1, 1987, and before December 31, 1995 (section 1879(g) of the Act).

#### B. Dependent Services

When it is determined that Medicare payment will be made under the limitation on liability provision for claims for items or services that were denied for one of the reasons specified in section II.A. of this Ruling, the payment determination includes claims for any dependent services that are denied as an indirect result of these

denials. This longstanding HCFA policy is based on the fact that the cause for denial of payment for the qualifying service is the primary cause for denial of the dependent services. For example, where a particular qualifying service is denied as not reasonable and necessary under section 1862(a) of the Act, lack of medical necessity is the underlying reason for the denial of the dependent services. Therefore, if the limitation on liability protection applies to the denial of the qualifying service, it will also apply to the dependent service.

For example, under sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act, home health aide services can be covered only if a beneficiary needs intermittent skilled nursing care. When coverage is denied for intermittent skilled nursing services (the qualifying primary services) under section 1862(a)(1) or (9) of the Act, home health aide services (the dependent services) likewise are not covered. In such cases, if Medicare payment is made under the limitation on liability provision for the primary services, it would be made for the dependent services as well, provided the services are otherwise covered (that is, all other conditions for payment of the dependent services are met including a physician's certification of the need for the dependent services and proof that the services are reasonable and necessary).

C. Reduced Payment Determinations Based on Reasonable and Necessary Levels of Care

The limitation on liability protection may also be applicable if a reduction in the level of payment occurs because the furnished services or items are at a level higher than was reasonable and necessary to meet the needs of the patient. This is because Medicare payment for the difference between reasonable and necessary services and items and those actually furnished is denied on the basis of section 1862(a)(1)(A) of the Act as not reasonable and necessary. For example, if it is determined that the level of care furnished by a hospice (such as continuous home care) was not reasonable and necessary under section 1862(a)(1)(A) because the care could have been given at a lower level (such as routine home care), Medicare payment under the limitation on liability provision may be made for the difference in reimbursement between the denied continuous home care and the approved routine home care if both the beneficiary and provider did not know, or could not reasonably have been expected to know, that payment would not be made for the higher level of care.

**III. DENIALS FOR WHICH THE LIMITATION ON LIABILITY PROVISION DOES NOT APPLY**

Medicare payment under the limitation on liability provision cannot be made when Medicare coverage is denied on any basis other than one of the provisions of the law specified in section II.A. of this Ruling. There are

certain claims, however, that may appear to involve a question of medical necessity, as described in section 1862(a)(1) of the Act, but the actual Medicare payment denial is based on a statutory provision other than section 1862(a)(1). Under these circumstances, Medicare payment under the limitation on liability provision cannot be made because the denial is not based on one of the statutory provisions specified in section II.A. of this Ruling.

Section 1879(a) of the Act provides that Medicare payment will be made under the limitation on liability provision "when a determination is made that, by reason of section 1862(a)(1) or (9) or by reason of a coverage denial described in subsection (g), payment may not be made under Part A or Part B" (Emphasis added) and the conditions described in section 1879(a)(2) are met. The statute thus explicitly restricts the application of the limitation on liability provision to cases that are decided on one of the statutory grounds we have specified in section II.A. of this Ruling. We believe that, in so providing, the Congress recognized that the issue of medical necessity of a service or item need never be reached if it were determined that the service or item would not otherwise be covered under the statute.

For example, when a Part B claim is submitted for ambulance services, the first step in processing the claim is to determine whether the services meet the requirements of section 1861(s)(7) of the Act (that is, to ascertain that

other methods of transportation are contraindicated) and, therefore, may be covered services under the Medicare statute. If other methods of transportation are contraindicated (and all other regulatory criteria met), only then must the Medicare contractor determine if the ambulance services are "reasonable and necessary" under section 1862(a)(1). If other methods of transportation are not contraindicated, there is no reason for the Medicare contractor to make a medical necessity determination under section 1862(a)(1) because the services have already been determined to be not otherwise covered under the Medicare statute.

The legislative history also suggests that the Congress excluded other types of cases from the limitation on liability protection because it recognized that beneficiaries and providers, practitioners, and other suppliers are aware or should be aware that Medicare will not pay for those services, as evidenced by the following statement in the Senate Finance Committee Report on the limitation on liability provisions (S. Rep. No. 90-1230, 92nd Cong., 2nd Sess. 294-95(1972)):

"Where expenses were incurred for clearly noncovered services, such as routine physical checkups, eyeglasses or eye examinations to determine the refractive state of the eyes, hearing aids or examination therefor, routine

dental service or immunizations, there will be a presumption made that the beneficiary and/or the provider were aware, or should have been aware, of the fact that the services were not covered."

In other words, the Congress concluded that there was no need to apply the limitation on liability provision to individuals who had obtained or furnished clearly noncovered services such as those listed in the report. Therefore, it is our position that when items or services are denied for any reason other than one of the specific statutory bases for denial described in section II.A. of this Ruling, limitation on liability cannot be applied.

Examples of circumstances in which Medicare payment under the limitation on liability provision cannot be made because the actual Medicare payment denial is based on a statutory provision other than section 1862(a)(1) include, but are not limited to, the following:

- Payment for the additional cost of a private room in a hospital or SNF is denied when the privacy accommodations are not required for medical reasons. Medicare payment for the additional cost is denied on the basis of section 1861(v)(2) of the Act.
- Payment for a dressing is denied because it does not meet the definition for "medical and other health services" in section 1861(s)(5) of the Act. Accordingly, Medicare

payment is denied on the basis of section 1861(s)(5) of the Act.

- Payment for ambulance services is denied because transportation by other means is not contraindicated or because regulatory criteria specified in 42 CFR 410.40, such as those relating to destination or nearest appropriate facility, are not met. In such circumstances, Medicare payment is denied on the basis of section 1861(s)(7) of the Act.

- Payment is denied for deluxe features of an item of durable medical equipment and is not based on medical necessity.

Another situation in which the protection under the limitation on liability provision cannot be afforded is if a beneficiary is enrolled under a Medicare contract with a prepaid health care organization (that is, health maintenance organization (HMO), competitive medical plan (CMP), or health care prepayment plan (HCPP)) that assumes financial responsibility for direct payment to a provider, practitioner, or other supplier for items or services furnished to the beneficiary under the terms of its contract. In those situations, since the provider, practitioner, or other supplier is paid directly by the prepaid health care organization, and not by a Medicare fee-for-service contractor, the limitation on liability protection cannot apply because of the inability in that

context to assign liability in ways envisioned under the statute. For example, section 1879 of the Act provides for Medicare payment to be made when the beneficiary and the provider, practitioner, or other supplier did not know, and could not reasonably have been expected to know, that Medicare payment would be denied. However, in the prepaid health care context, the Medicare program is insulated from liability in those situations in which the prepaid health care organization assumes financial responsibility for direct payment of an item or service to the provider, practitioner, or other supplier. Although certain prepaid health care organizations may perform the function of determining Medicare coverage, they do not act strictly as an agent of the Medicare program, as do Medicare contractors. Section 1879 was not intended to assign liability in cases in which a health care organization that authorized or furnished noncovered services under contract with Medicare makes direct payment to a subcontractor. We, therefore, conclude that the issue of liability in the prepaid health care context is not governed by section 1879.

There are situations, however, where Medicare enrollees of HCPPs and cost HMOs/CMPs may receive services and have Medicare payment made through Medicare contractors, instead of the prepaid health care organization making direct payment to the provider, practitioner, or other supplier. In these situations, the limitation on liability protection

may apply to the enrollee if services are denied on one of the specific statutory bases described in section II.A. of this Ruling. These situations include the following:

- The HMO/CMP is a cost-reimbursed HMO with a contract under section 1876 of the Act, and the service in question is a provider service which, although it is being arranged for through the HMO/CMP, is a service that the HMO/CMP has opted to have paid by a Medicare contractor under the provisions of section 1876(h)(2)(A);
- The service is one that a Medicare enrollee of an HCPP or a cost HMO/CMP chooses to receive "out of plan" (that is, without having arranged for the service through the HMO/CMP), and the service is, therefore, being billed through the Medicare contractor; or
- The provider, practitioner, other supplier, or beneficiary submits a claim for the service through the Medicare contractor as a result of the HCPP or cost HMO/CMP's refusal to pay for the service.

Medicare enrollees of "risk" HMOs/CMPs under section 1876 of the Act are prohibited from having Medicare program payments made through Medicare contractors. For these enrollees, the only program payment is the capitation payable to the HMO/CMP for each enrolled Medicare beneficiary. Therefore, the limitation on liability provision is never extended to enrollees of the "risk" HMOs/CMPs.

#### IV. DETERMINING KNOWLEDGE

For the protection under the limitation on liability provision to be afforded, lack of prior knowledge that Medicare payment for the item or service would be denied must first be established. Two determinations must be made to establish knowledge: (1) Whether and when the beneficiary knew or should have known that Medicare payment for the item or service would be denied, and (2) whether and when the provider, practitioner, or other supplier knew or should have known that Medicare payment for the item or service would likely be denied. The principles for determining knowledge described below apply to determinations of knowledge with respect to denials under section 1879(a) through (g) of the Act for which Medicare payment may be made, as well as to those under section 1879(h) of the Act, for which refunds may be required.

##### A. Criteria For Determining Beneficiary Knowledge

Section 1879(a)(2) of the Act requires that the beneficiary "did not know, and could not reasonably have been expected to know, that payment would not be made\* \* \*," for items or services that are excluded from coverage as not reasonable and necessary or as custodial care, in order for the limitation on liability protection to be afforded. This includes knowledge based on written notice having been provided to the beneficiary, as well as any other means from

which it is determined that the beneficiary knew, or should have known, that payment would not be made.

Our regulations at 42 CFR 411.404 (Criteria for determining that a beneficiary knew that services or items were excluded from coverage as custodial care or as not reasonable and necessary) provide one basis for determining beneficiary knowledge that payment would not be made for items or services that are excluded from coverage as not reasonable and necessary or as custodial care. These regulations provide that a beneficiary will be considered to know, based on written notice, that services or items were excluded from coverage as not reasonable and necessary or as custodial care. Under these regulations, there is a presumption that he or she knew, or could reasonably have been expected to know, that Medicare payment for a service or item would be denied if advance written notice has been given either to the beneficiary or to someone acting on his or her behalf that the items or services were not covered.

In accordance with § 411.404, a written notice of Medicare denial of payment must contain sufficient information to enable the beneficiary to understand the basis for the denial. Such notice constitutes sufficient documentation to show that the beneficiary had prior knowledge of the likelihood of denial of that claim, and of all future claims filed by or on behalf of the beneficiary that involve that same or a similar item or service. In

addition, a written notice of Medicare denial of payment from a Medicare contractor for a previous claim for a particular service or item received by the beneficiary serves as prior written notice for all future claims filed by or on behalf of the beneficiary that involve that same or a similar service or item.

Generally, the required written notice of the likelihood of denial must be furnished to the beneficiary (or the person acting on his or her behalf) by:

- A provider, practitioner, or other supplier before the service or item was furnished.
- The provider, after the Medicare contractor, during the course of the patient's stay, advised the provider that covered care had ceased.
- A provider utilization review committee that, on admission or during the patient's stay, advised that the patient no longer required covered care.
- The Medicare contractor.

While § 411.404 provides criteria for beneficiary knowledge based on written notice, section 1879(a)(2) of the Act specifies only that knowledge must not exist in order to apply the limitation on liability protection. If it is clear and obvious that a beneficiary in fact did know, prior to receiving a service or item, that Medicare payment for that service or item would be denied, the administrative presumption favorable to the beneficiary referred to in

§ 411.404, is rebutted. For example, if the beneficiary admits that he or she had prior knowledge that payment for a service or item would be denied, no further evidence is required; the absence of a written notice is moot.

The failure of any provider, practitioner, or other supplier to furnish to a beneficiary proper advance notice of the likelihood of denial is not sufficient to afford the beneficiary the protection of the limitation on liability provision if the contractor has proof that the beneficiary, nonetheless, had the requisite knowledge that the service would be denied. In any case in which the contractor has such evidence of prior knowledge on the beneficiary's part, the beneficiary must be held liable under the limitation on liability provision.

B. Determining Provider, Practitioner, or Other Supplier Knowledge

1. General

The Medicare contractors determine, based on the information they maintain and/or disseminate to a particular provider, practitioner, or other supplier, whether the provider, practitioner, or other supplier actually had prior knowledge that services or items would likely be denied or whether knowledge reasonably could have been expected. The determination of actual or expected knowledge is based on all the relevant facts pertaining to each particular denial.

2. Criteria For Determining Practitioner and Other Supplier Knowledge

In accordance with 42 CFR 411.406 (Criteria for determining that a provider, practitioner, or other supplier knew that items or services were excluded from coverage as custodial care or as not reasonable and necessary) and § 7300.5 of the Medicare Carriers Manual, evidence that the practitioner or other supplier did, in fact, know or should have known that Medicare would not pay for a service or item includes:

- A Medicare contractor's prior written notice to the practitioner or other supplier of Medicare denial of payment for similar or reasonably comparable services or items;
- Our general notices to the medical community of Medicare payment denial of services and items under all or certain circumstances. (Our notices include, but are not limited to, manual instructions, bulletins, carriers' written guides, and directives); and
- Provision of the services and items was inconsistent with acceptable standards of practice in the local medical community (refer to section V. of this Ruling).

If any of the circumstances described above exists, a practitioner or other supplier is held to have knowledge.

The practitioner or other supplier is presumed liable for denied services or items at the initial determination, with one exception. If a practitioner or other supplier

gives the beneficiary proper written advance notice that Medicare will likely deny payment for the service or item to be furnished, and so documents the claim, the beneficiary is held liable for the denied services or items at the initial determination. The advance notice must clearly identify the particular service or item, must state that the practitioner or other supplier believes Medicare is likely to deny payment as not reasonable and necessary for the particular service or item, and must give the basis for the practitioner or other supplier's belief that Medicare is likely to deny payment for the service or item, in order to protect the practitioner or other supplier from liability. The beneficiary must be told why the practitioner or supplier is predicting Medicare denial of payment so that the beneficiary can make an informed decision whether to receive the service or item and to pay for it out-of-pocket. Such a notice constitutes proof that the beneficiary had prior knowledge that Medicare payment would be denied for the service or item in question.

In our program instructions (Medicare Carriers Manual § 7300.5(A)), we suggest that the practitioner or supplier have the beneficiary sign the agreement. If a beneficiary's signature is absent, in case of a dispute as to the agreement, the beneficiary's allegations regarding the notice will be given credence.

In summary, if the practitioner or other supplier can show that (1) the beneficiary received proper written advance notice, or (2) the practitioner or other supplier did not know, and could not reasonably have been expected to know, that Medicare would not pay for the service or item, then, absent evidence to the contrary, the medical review entity (in this case the carrier) must find that the practitioner or other supplier is not liable.

### 3. Criteria For Determining Provider Knowledge

#### (a) Favorable Presumption

##### (1) Background

Administrative presumptions ("favorable presumptions") are used for certain categories of providers in determining whether a provider had prior knowledge that Medicare payment for services or items would be denied. We established favorable presumptions in July 1973 because, when the Congress passed the limitation on liability provisions in section 1879 of the Act (section 213 of the Social Security Amendments of 1972, Public Law 92-603), providers were not as knowledgeable about Medicare coverage rules as they later became. In addition, written guidelines were not as explicit as they are now. Therefore, we developed formulas, using statistical denial rate criteria, that allowed providers who usually made correct coverage determinations to be paid for their few incorrect coverage determinations under the presumption that they did not have prior knowledge

that Medicare payment for the services or items would be denied.

The basis for applying the favorable presumption mechanism, based on the statistical denial rate criteria, was established in our regulations at 42 CFR 405.195 and 405.196. These regulations specified, in part, that a favorable presumption would be allowed if we found that, on the basis of bills submitted, the provider effectively distinguished between cases in which the services or items furnished by the provider were covered under Medicare and cases in which they were excluded from coverage. The favorable presumption mechanism applied from July 1973 until February 1986 to hospitals, SNFs, and home health agencies (HHAs).

On February 21, 1986, we published a final rule in the Federal Register, 51 FR 6222, which added a new 42 CFR 405.336 and removed 42 CFR 405.195 and 405.196. These changes to the regulations revised the way we applied limitation on liability for providers and removed the administrative mechanism of favorable presumption in determining whether a hospital, SNF, or HHA should be held liable for furnishing a service or item for which Medicare payment is denied.

In April 1986, sections 9126(c) and 9205 of the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA), Public Law 99-272, reinstated the use of a

favorable presumption for SNFs (including SNF swing beds) and HHAs, but not for hospitals. Under COBRA, a statistical denial rate criterion remained in effect, which was to be applied in the same manner as under the regulations in effect as of July 1, 1985 (42 CFR 405.195 and 405.196).

In October 1986, section 9305(f) of the Omnibus Budget Reconciliation Act of 1986 (OBRA '86), Public Law 99-509, extended the favorable presumption mechanism to the hospice program. Section 9305(g) of OBRA '86 extended the limitation on liability provision to HHA denials if Medicare payment for home health services a beneficiary received is denied because the beneficiary was not "homebound" or did not require "intermittent skilled nursing care" (as required by sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act). This provision was applicable only to services furnished from July 1, 1987, to October 1, 1989 (section 9305(g)(3) of OBRA '86).

#### (2) Extended Application of Favorable Presumptions

Under statutory provisions, favorable presumptions were extended to apply to HHAs, hospices, and SNFs (including SNF swing beds). The following provisions of the Omnibus Budget Reconciliation Act of 1990 (OBRA '90) extended the application of favorable presumptions until December 31, 1995:

- Section 4008(a)(1) amended section 9126(c) of COBRA for SNFs (including SNF swing beds);

- Section 4008(a)(2) amended section 9305(f) of OBRA '86 for hospices; and
- Section 4207(b)(3) amended section 9305(g) of OBRA '86 for claims for home health services that are denied because the beneficiary was not "homebound" or did not require "intermittent skilled nursing care" (as required by sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act).

(OBRA '90 inadvertently omitted a favorable presumption extension for HHA medical necessity denials by failing to amend section 9205 of COBRA. Therefore, we issued a Program Memorandum (Transmittal No. AB-91-6, July 1991) that administratively extended the HHAs' favorable presumption for medical necessity denials until section 4207(b)(3) of OBRA '90 could be appropriately amended. Section 158(b) of the Social Security Act Amendments of 1994 made this amendment.)

**(3) Criteria For Determining If an HHA, SNF, or Hospice Merits a Favorable Presumption**

As a means of determining whether an HHA, SNF, or hospice merits a favorable presumption, we established and implemented two statistical formulas that provide a measure of the SNF's, HHA's, or hospice's accuracy in assessing whether services and items are covered or noncovered, in accordance with the regulations that existed under 42 CFR 405.195 and 405.196. The first formula calculates the "denial rate," which is a quarterly measurement used to

indicate whether the SNF, HHA, or hospice can generally make correct judgments concerning the coverage of services and items. Denial of very few claims billed as covered is held to demonstrate a provider's ability to make correct coverage assessments under most circumstances. Thus, when a provider does not exceed the denial rate established under COBRA (5 percent of claims submitted for SNFs (including SNF swing beds) and 2.5 percent of claims submitted for HHAs and hospices), a favorable presumption is employed.

The second formula calculates the demand bill "reversal rate," which is a quarterly measurement used to indicate whether the SNF, HHA, or hospice can generally make correct judgments concerning the noncoverage of services and items. A demand bill is a claim for services or items that the provider believes are not covered but which the provider must submit at the demand of the beneficiary or the beneficiary's representative. If the Medicare contractor determines that one or more services or items on such a claim actually do qualify for Medicare payment, the provider's assessment that the service or item is not covered is reversed. Like the denial rate, reversal of very few claims billed as noncovered is held to demonstrate a provider's ability to make correct noncoverage judgments under most circumstances. Thus, when a provider does not exceed the established reversal rate criterion (for SNFs (including SNF swing beds), less than 20 reversals out of

100 or fewer demand bills submitted, or no more than 20 percent if more than 100 demand bills are submitted; for HHAs and hospices, less than 10 reversals out of 100 or fewer demand bills submitted, or no more than 10 percent if more than 100 demand bills are submitted), a favorable presumption is employed.

As long as an SNF, HHA, or hospice remains within both the denial rate threshold and the demand bill reversal rate threshold, all of its denied claims will be processed as if the provider had no prior knowledge that the claims would be denied. However, such a favorable presumption is rebutted and no Medicare payment will be made if it is clear and obvious that the provider knew that particular services or items would be denied (see section IV.B.3.(b) of this Ruling).

We note that a favorable presumption can be employed for purposes of determining a provider's limitation on liability under section 1879 only during a prepayment review of the claim. A favorable presumption amounts to an automatic decision that a provider did not have knowledge that payment would be denied, without a further review of the case to see if there is evidence to the contrary. Therefore, there is no longer a need for a presumption when a postpayment audit review is conducted, because the claim is being reviewed and the reviewer will know, based on the specific facts of the case, whether the provider had

knowledge that payment would be denied on the basis that services and items were not reasonable and necessary. Therefore, a favorable presumption is not relevant for purposes of a postpayment audit review.

In addition, for appeal purposes, the existence/non-existence of a favorable presumption is determined based on a provider's statistical standing at the time the initial claim determination is made, not at the time of the appeal hearing.

(b) When a Provider Is Always Considered To Have Prior Knowledge

No Medicare payment will be made to any provider for any claim if previous notification was given or if for any other reason the provider clearly should have known that the claim would be denied. This includes providers that have a favorable presumption, since the presumption is rebutted where there is clear and obvious evidence that the provider knew or should have known that the services or items at issue would be denied.

Sections 9126(c) and 9205 of COBRA and section 9305(f) of OBRA '86, which reinstated the use of a favorable presumption, require application of the presumption in the manner provided in regulations in effect as of July 1, 1985 (42 CFR 405.195 and 405.196). Section 405.195(a) explicitly provided for a rebuttable presumption. General legal principles provide that a rebuttable (or "disputable")

presumption controls unless and until it is invalidated by proof of evidence contrary to the presumption. If evidence contrary to the presumption is found, the presumption disappears and the case stands upon the facts and the reasonable inferences to be drawn therefrom. Therefore, in all cases in which there is evidence that a provider had knowledge or should have had knowledge that services or items would be denied, the favorable presumption is rebutted.

Criteria for determining whether a provider had knowledge or should have had knowledge that services or items would be denied are in regulations at 42 CFR 411.406 and in § 3439.B. through 3439.G. of the Medicare Intermediary Manual. These sources cite various forms and methods of notification that provide sufficient evidence that the provider knew or should have known that the services or items would be denied. Such notices are sufficient notice for all subsequent claims involving that same service or item under similar or reasonably comparable conditions. In general, notification often is provided by one of the following sources:

- The provider's utilization review committee informed the provider in writing that the services were not covered;
- The provider previously submitted a no-payment claim (i.e., a pro forma filing in which no payment is sought, rather, only a formal payment denial determination is

requested), or submitted a claim for Medicare payment only at the request of the beneficiary;

- The provider issued a written notice of the likelihood of Medicare payment denial for a service or item to the beneficiary;

- We have issued manuals, bulletins, memoranda, etc., advising providers of the noncoverage of a particular service or category of services;

- A Medicare contractor previously issued a written notice to the provider that Medicare payment for a particular service or item is denied. This also includes notification of PRO screening criteria specific to the condition of the beneficiary for whom the furnished services are at issue and of medical procedures subject to preadmission review by the PRO;

- The provider was previously notified by telephone and/or in writing that care is not covered or that covered care has ended; or

- A general bulletin or newsletter was issued to providers advising that a specific service or item is not considered reasonable and necessary.

The provider is accountable for information contained in the patient's medical records, such as the patient's medical chart, attending physicians' notes, or similar records, since these are provider records. Evidence based upon medical records, such as that described in the

following list, clearly indicates knowledge that Medicare payment for services or items would be denied:

- A physician clearly indicated in the patient's medical record that the patient no longer needed the services or the level of care provided;
- The physician indicated the patient could be discharged; or
- The attending physician refused to certify or recertify the patient's need for a particular level of care covered by Medicare because he/she determined that the patient does not require a covered level of care.

#### **V. ACCEPTABLE STANDARDS OF PRACTICE--APPLICATION**

In situations in which services or items furnished do not meet locally acceptable standards of practice, the provider, practitioner, or other supplier is considered to have known that Medicare payment for the services or items would be denied. Providers, practitioners, and other suppliers are always responsible for knowing locally acceptable standards of practice; their local licensure is premised on the assumption that they have such knowledge. Medicare payment to providers, practitioners, or other suppliers is premised on the presumption that they have such knowledge, as evidenced by their licensure. No other evidence of knowledge of local medical standards of practice is necessary.

Medicare contractors, in determining what "acceptable standards of practice" exist within the local medical community, rely on published medical literature, a consensus of expert medical opinion, and consultations with their medical staff, medical associations, including local medical societies, and other health experts. "Published medical literature" refers generally to scientific data or research studies that have been published in peer-reviewed medical journals or other specialty journals that are well recognized by the medical profession, such as the "New England Journal of Medicine" and the "Journal of the American Medical Association." By way of example, consensus of expert medical opinion might include recommendations that are derived from technology assessment processes conducted by organizations such as the Blue Cross and Blue Shield Association or the American College of Physicians, or findings published by the Institute of Medicine.

#### **VI. FRAUD AND ABUSE--APPLICATION**

Generally, the protection under the limitation on liability provision cannot be afforded to providers, practitioners, or other suppliers if a formal finding of fraud or abuse has been made with regard to a provider's, practitioner's, or other supplier's billing practices. In cases in which a formal finding of fraud or abuse is made, an immediate finding of liability for the provider, practitioner, or other supplier results.

VII. PAYMENT UNDER LIMITATION ON LIABILITY

A. Beneficiary Is Determined To Be Not Liable

For claims denied solely on the basis of one of the provisions listed in section II.A of this Ruling and it has been determined that the beneficiary did not know and could not reasonably have been expected to know that the service or item would be denied, the following are the effects:

- Under section 1879(a)(2) of the Act and the accompanying regulations at 42 CFR 411.400(a)(2), the Medicare program must make payment when the provider, practitioner, or other supplier did not know and could not reasonably have been expected to know that the services or items would be denied. In these instances, the usual deductible and coinsurance amounts apply. The number of days or visits paid for under the limitation on liability provision is charged to the beneficiary's utilization record. Medicare payment may also be made under section 1154(a)(2)(B) of the Act and 42 CFR 411.400(b)(2) for a 1-day "grace period" after the date of notice to the provider or to the beneficiary, whichever is earlier, if additional time is needed to arrange for post-discharge care. If it is determined thereafter by a PRO or the Medicare contractor that even more time is required in order to arrange post-discharge care, 1 additional "grace period" day is paid. Initial approval of 2 or more "grace period" days is not permitted. The "grace period" is applicable

only if circumstances would have permitted Medicare program payment under section 1879(a)(1) and (2) of the Act and 42 CFR 411.400(b)(2), that is, protection under the limitation on liability provision was afforded both to the beneficiary and the provider;

- Under section 1879(b) of the Act and 42 CFR 411.402, Medicare does not make payment when it is determined that the provider, practitioner, or other supplier had prior knowledge that Medicare would deny payment for services or items or could reasonably have been expected to have had this knowledge. In these instances, the beneficiary is not responsible for paying the deductible and coinsurance charges related to the denied claim and the beneficiary's Medicare utilization record is not charged for the services and items furnished, effective for all services or items furnished on or after January 1, 1988.

In addition, under section 1879(b) and 42 CFR 411.402 et seq., if the provider, practitioner, or other supplier is considered to be liable and requests and receives payment from the beneficiary or any person(s) who assumed financial responsibility for payment of the beneficiary's expenses, the Medicare program indemnifies the beneficiary or other person(s) for any amounts paid by the beneficiary. This includes any deductible or coinsurance charges paid by or on behalf of the beneficiary. Further, these indemnification

payments are considered an overpayment to the provider, practitioner, or other supplier.

**B. Beneficiary Is Determined To Be Liable**

Under section 1879(c) of the Act and 42 CFR 411.404, the beneficiary is held to be liable when it is determined that he or she had prior knowledge that Medicare payment for the service or item would be denied or could reasonably have been expected to have had such knowledge. In these instances, the beneficiary is held responsible for expenses incurred for services or items for which Medicare payment is denied, regardless of whether the provider, practitioner, or other supplier had knowledge. The Medicare program makes no payment to the beneficiary, provider, practitioner, or other supplier.

**VIII. APPEALS**

**A. Beneficiary's Right To Appeal**

If the Medicare contractor determines that the beneficiary knew or could reasonably have been expected to know that Medicare payment for the services or items furnished would be denied, the beneficiary has appeal rights for both the determination holding him or her liable for the cost of the denied services or items and the substantive coverage determination. In addition, if Medicare pays the claim in accordance with section 1879 of the Act (that is, the Medicare contractor determines that neither the beneficiary nor the provider, practitioner, or other

supplier knew or could reasonably have been expected to know that the services or items would be denied), the beneficiary may still appeal the coverage determination.

B. Provider's Right to Appeal

If the Medicare contractor finds (1) that the beneficiary or the provider (or both) knew or could reasonably have been expected to know that Medicare payment for the services or items furnished would be denied, or (2) that the beneficiary did not know and could not reasonably have been expected to know that Medicare payment for the services or items furnished would be denied, and the beneficiary chooses not to exercise his or her appeal rights, the provider may appeal both the coverage and the liability determinations. However, if Medicare pays the claim in accordance with section 1879 of the Act, the provider may not appeal the coverage determination.

C. Practitioner's and Other Supplier's Right to Appeal

When it is determined by the Medicare contractor that a practitioner who accepts assignment or an other supplier who accepts assignment knew or could reasonably have been expected to know that Medicare payment for the services or items furnished would be denied, the practitioner or other supplier may appeal both the coverage and the liability determinations. In addition, if Medicare pays the claim in accordance with section 1879 of the Act, the practitioner

who accepts assignment or the other supplier who accepts assignment may still appeal the coverage determination.

D. PRO Determinations

Under title XI of the Act, when a PRO determines that a provider or practitioner is liable for payment of denied services and items furnished a beneficiary, the provider or practitioner may appeal the coverage determination and/or the liability determination only through the reconsideration or review level of appeal. At any appeal beyond the reconsideration or review level, the provider or practitioner may challenge only the PRO's liability determination, not the substantive coverage determination.

Medicare Part A limitation on liability determinations are governed by procedures in 42 CFR part 405, subpart G. Medicare Part B limitation on liability determinations are governed by procedures in 42 CFR part 405, subpart H, and 42 CFR part 473. When the PRO makes a limitation on liability determination on a Part B claim, which is governed by subpart H of 42 CFR part 405, either the PRO or the carrier may conduct the fair hearing. Part B ALJ hearings and Appeals Council review are conducted pursuant to the procedures outlined in HCFA and SSA's Federal Register notice of June 1, 1988, 53 FR 20023 (June 1, 1988), unless superseded by subsequent regulations.

**IX. EFFECTIVE DATE**

This Ruling is effective December 31, 1995.

Dated: 12/21/95

  
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Bruce C. Vladeck,  
Administrator,  
Health Care Financing  
Administration



# HCFA Rulings

Department of Health  
and Human Services

Health Care Financing  
Administration

Ruling No

95-1

Date

December 1995

HCFA Rulings are decisions of the Administrator that serve as precedent final opinions and orders and statements of policy and interpretation. They provide clarification and interpretation of complex or ambiguous provisions of the law or regulations relating to Medicare, Medicaid, Utilization and Quality Control Peer Review, and related matters.

HCFA Rulings are binding on all HCFA components, the Provider Reimbursement Review Board, the Medicare Geographic Classification Review Board, the Appeals Council, and Administrative Law Judges who hear Medicare appeals. These Rulings promote consistency in interpretation of policy and adjudication of disputes.

This Ruling states the policy of the Health Care Financing Administration concerning the requirements for determining if Medicare payment will be made under the limitation on liability provisions, section 1879 of the Social Security Act, to a provider, practitioner, or other supplier for certain services and items for which Medicare payment is denied.



**MEDICARE PROGRAM**

**Hospital Insurance (Part A) and Supplementary Medical Insurance (Part B)**

**REQUIREMENTS FOR DETERMINING LIMITATION ON LIABILITY OF A MEDICARE BENEFICIARY, PROVIDER, PRACTITIONER, OR OTHER SUPPLIER FOR CERTAIN SERVICES AND ITEMS FOR WHICH MEDICARE PAYMENT IS DENIED.**

**PURPOSE:** This Ruling states the policy of the Health Care Financing Administration concerning the requirements for determining if Medicare payment will be made under the limitation on liability provision, section 1879 of the Social Security Act, to a provider, practitioner, or other supplier for certain services and items for which Medicare payment is denied.

**CITATIONS:** Sections 1142, 1154, 1814, 1815, 1833, 1834, 1861, 1862, 1866, and 1879 of the Social Security Act (42 USC 1320b-12, 1320c, 1395f, 1395g, 1395l, 1395m, 1395x, 1395y, 1395cc, and 1395pp) and 42 CFR 411.400, 411.402, 411.404 and 411.406.

RULING APPLICABLE TO DETERMINING LIMITATION ON LIABILITY OF  
A MEDICARE BENEFICIARY, PROVIDER, PRACTITIONER, OR OTHER  
SUPPLIER FOR CERTAIN SERVICES AND ITEMS FOR WHICH MEDICARE  
PAYMENT IS DENIED

I. BACKGROUND

Section 1879 of the Social Security Act (the Act) provides financial relief to beneficiaries, providers, practitioners, and other suppliers by permitting Medicare payment to be made, or requiring refunds to be made, for certain services and items for which Medicare payment would otherwise be denied. We refer to this section of the Act as "the limitation on liability provision."

The Medicare program currently pays out millions of dollars each year under the limitation on liability provision. The purpose of this Ruling is to provide a detailed clarification of our policy with regard to the limitation on liability provision to ensure that Medicare payment under the policy is made in an appropriate and consistent manner.

Medicare payment under the limitation on liability provision is dependent upon two primary factors. First, the claims for the services or items furnished must have been denied for one of the following reasons. The services or items were:

- not reasonable and necessary under section 1862(a)(1) of the Act;

- for custodial care and, therefore, not covered under section 1862(a)(9) of the Act;
- denied because the beneficiary was unintentionally, inadvertently, or erroneously placed into a noncertified bed (one that does not meet the requirements of section 1861(e) or (j) of the Act), as referenced by section 1879(e) of the Act; or
  - noncovered home health services furnished to a beneficiary who was not "homebound" or who did not require "intermittent skilled nursing care" (as required by sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act), as referenced by section 1879(g) of the Act.

The second factor in determining if Medicare payment is made under the limitation on liability provision is whether the beneficiary and/or the provider, practitioner, or other supplier knew or could reasonably have been expected to know that the items or services (for which Medicare payment was denied on one of the bases listed above) were excluded from coverage. A determination of whether the protection under the limitation on liability provision can be afforded for a denied claim is made as a result of a prepayment medical review or a postpayment audit review.

Section 1879(h) of the Act provides for refunds by the supplier to the beneficiary in the case of certain claims for durable medical equipment (DME) for which payment is denied. This Ruling deals primarily with section 1879(a)

through (g), whereby Medicare payment may be made, or the beneficiary may be indemnified, under certain circumstances.

**II. COVERAGE DENIALS TO WHICH THE LIMITATION ON LIABILITY PROVISION APPLIES**

**A. Statutory Bases**

A coverage determination for an item or service must be made before there can be a decision with respect to whether Medicare payment may be made under the limitation on liability provision. Medical review entities, acting for the Secretary, are authorized to make the coverage determinations. These entities include fiscal intermediaries, carriers, and Utilization and Quality Control Peer Review Organizations (PROs). In this Ruling we refer to these entities collectively as Medicare contractors. These entities must act in accordance with the Medicare statutes, regulations, national coverage instructions, accepted standards of medical practice, and HCFA Rulings when making coverage determinations.

The claims payment and beneficiary indemnification provisions (sections 1879(a) and (b)) of the limitation on liability provision are applicable only to claims for beneficiary items or services submitted by providers, or by practitioners and other suppliers that have taken assignment, and only to claims for services, not otherwise statutorily excluded, that are denied on the basis of section 1862(a)(1), 1862(a)(9), 1879(e), or 1879(g) of the Act, which, under current law, include the following:

- Services and items found to be not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member (section 1862(a)(1)(A) of the Act).
- Pneumococcal vaccine and its administration, influenza vaccine and its administration, and hepatitis B vaccine and its administration, furnished to an individual at high or intermediate risk of contracting hepatitis B, that are not reasonable and necessary for the prevention of illness (section 1862(a)(1)(B) of the Act).
- Services and items which, in the case of hospice care, are not reasonable and necessary for the palliation or management of terminal illness (section 1862(a)(1)(C) of the Act).
- Clinical care services and items furnished with the concurrence of the Secretary and, with respect to research and experimentation conducted by, or under contract with, the Prospective Payment Assessment Commission or the Secretary, that are not reasonable and necessary to carry out the purposes of section 1886(e)(6) of the Act (which concerns identification of medically appropriate patterns of health resources use) (section 1862(a)(1)(D) of the Act).
- Services and items that, in the case of research conducted pursuant to section 1142 of the Act, are not reasonable and necessary to carry out the purposes of that section (which concerns research on outcomes of health care services and procedures) (section 1862(a)(1)(E) of the Act).

- Screening mammography that is performed more frequently than is covered under section 1834(c)(2) of the Act or that is not conducted by a facility described in section 1834(c)(1)(B) of the Act and screening pap smears performed more frequently than is provided for under section 1861(nn) of the Act (section 1862(a)(1)(F) of the Act).
- Custodial care (section 1862(a)(9) of the Act).
- Inpatient hospital services or extended care services if payment is denied solely because of an unintentional, inadvertent, or erroneous action that resulted in the beneficiary's transfer from a certified bed (one that does not meet the requirements of section 1861(e) or (j) of the Act) in a skilled nursing facility (SNF) or hospital (section 1879(e) of the Act).
- Home health services determined to be noncovered because the beneficiary was not "homebound" or did not require "intermittent" skilled nursing care (as required by sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act) on or after July 1, 1987, and before December 31, 1995 (section 1879(g) of the Act).

**B. Dependent Services**

When it is determined that Medicare payment will be made under the limitation on liability provision for claims for items or services that were denied for one of the reasons specified in section II.A. of this Ruling, the payment determination includes claims for any dependent services that are denied as an indirect result of these

denials. This longstanding HCFA policy is based on the fact that the cause for denial of payment for the qualifying service is the primary cause for denial of the dependent services. For example, where a particular qualifying service is denied as not reasonable and necessary under section 1862(a) of the Act, lack of medical necessity is the underlying reason for the denial of the dependent services. Therefore, if the limitation on liability protection applies to the denial of the qualifying service, it will also apply to the dependent service.

For example, under sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act, home health aide services can be covered only if a beneficiary needs intermittent skilled nursing care. When coverage is denied for intermittent skilled nursing services (the qualifying primary services) under section 1862(a)(1) or (9) of the Act, home health aide services (the dependent services) likewise are not covered. In such cases, if Medicare payment is made under the limitation on liability provision for the primary services, it would be made for the dependent services as well, provided the services are otherwise covered (that is, all other conditions for payment of the dependent services are met including a physician's certification of the need for the dependent services and proof that the services are reasonable and necessary).

C. Reduced Payment Determinations Based on Reasonable and Necessary Levels of Care

The limitation on liability protection may also be applicable if a reduction in the level of payment occurs because the furnished services or items are at a level higher than was reasonable and necessary to meet the needs of the patient. This is because Medicare payment for the difference between reasonable and necessary services and items and those actually furnished is denied on the basis of section 1862(a)(1)(A) of the Act as not reasonable and necessary. For example, if it is determined that the level of care furnished by a hospice (such as continuous home care) was not reasonable and necessary under section 1862(a)(1)(A) because the care could have been given at a lower level (such as routine home care), Medicare payment under the limitation on liability provision may be made for the difference in reimbursement between the denied continuous home care and the approved routine home care if both the beneficiary and provider did not know, or could not reasonably have been expected to know, that payment would not be made for the higher level of care.

**III. DENIALS FOR WHICH THE LIMITATION ON LIABILITY PROVISION DOES NOT APPLY**

Medicare payment under the limitation on liability provision cannot be made when Medicare coverage is denied on any basis other than one of the provisions of the law specified in section II.A. of this Ruling. There are

certain claims, however, that may appear to involve a question of medical necessity, as described in section 1862(a)(1) of the Act, but the actual Medicare payment denial is based on a statutory provision other than section 1862(a)(1). Under these circumstances, Medicare payment under the limitation on liability provision cannot be made because the denial is not based on one of the statutory provisions specified in section II.A. of this Ruling.

Section 1879(a) of the Act provides that Medicare payment will be made under the limitation on liability provision "when a determination is made that, by reason of section 1862(a)(1) or (9) or by reason of a coverage denial described in subsection (g), payment may not be made under Part A or Part B" (Emphasis added) and the conditions described in section 1879(a)(2) are met. The statute thus explicitly restricts the application of the limitation on liability provision to cases that are decided on one of the statutory grounds we have specified in section II.A. of this Ruling. We believe that, in so providing, the Congress recognized that the issue of medical necessity of a service or item need never be reached if it were determined that the service or item would not otherwise be covered under the statute.

For example, when a Part B claim is submitted for ambulance services, the first step in processing the claim is to determine whether the services meet the requirements of section 1861(s)(7) of the Act (that is, to ascertain that

other methods of transportation are contraindicated) and, therefore, may be covered services under the Medicare statute. If other methods of transportation are contraindicated (and all other regulatory criteria met), only then must the Medicare contractor determine if the ambulance services are "reasonable and necessary" under section 1862(a)(1). If other methods of transportation are not contraindicated, there is no reason for the Medicare contractor to make a medical necessity determination under section 1862(a)(1) because the services have already been determined to be not otherwise covered under the Medicare statute.

The legislative history also suggests that the Congress excluded other types of cases from the limitation on liability protection because it recognized that beneficiaries and providers, practitioners, and other suppliers are aware or should be aware that Medicare will not pay for those services, as evidenced by the following statement in the Senate Finance Committee Report on the limitation on liability provisions (S. Rep. No. 90-1230, 92nd Cong., 2nd Sess. 294-95(1972)):

"Where expenses were incurred for clearly noncovered services, such as routine physical checkups, eyeglasses or eye examinations to determine the refractive state of the eyes, hearing aids or examination therefor, routine

dental service or immunizations, there will be a presumption made that the beneficiary and/or the provider were aware, or should have been aware, of the fact that the services were not covered."

In other words, the Congress concluded that there was no need to apply the limitation on liability provision to individuals who had obtained or furnished clearly noncovered services such as those listed in the report. Therefore, it is our position that when items or services are denied for any reason other than one of the specific statutory bases for denial described in section II.A. of this Ruling, limitation on liability cannot be applied.

Examples of circumstances in which Medicare payment under the limitation on liability provision cannot be made because the actual Medicare payment denial is based on a statutory provision other than section 1862(a)(1) include, but are not limited to, the following:

- Payment for the additional cost of a private room in a hospital or SNF is denied when the privacy accommodations are not required for medical reasons. Medicare payment for the additional cost is denied on the basis of section 1861(v)(2) of the Act.
- Payment for a dressing is denied because it does not meet the definition for "medical and other health services" in section 1861(s)(5) of the Act. Accordingly, Medicare

payment is denied on the basis of section 1861(s)(5) of the Act.

- Payment for ambulance services is denied because transportation by other means is not contraindicated or because regulatory criteria specified in 42 CFR 410.40, such as those relating to destination or nearest appropriate facility, are not met. In such circumstances, Medicare payment is denied on the basis of section 1861(s)(7) of the Act.
- Payment is denied for deluxe features of an item of durable medical equipment and is not based on medical necessity.

Another situation in which the protection under the limitation on liability provision cannot be afforded is if a beneficiary is enrolled under a Medicare contract with a prepaid health care organization (that is, health maintenance organization (HMO), competitive medical plan (CMP), or health care prepayment plan (HCPP)) that assumes financial responsibility for direct payment to a provider, practitioner, or other supplier for items or services furnished to the beneficiary under the terms of its contract. In those situations, since the provider, practitioner, or other supplier is paid directly by the prepaid health care organization, and not by a Medicare fee-for-service contractor, the limitation on liability protection cannot apply because of the inability in that

context to assign liability in ways envisioned under the statute. For example, section 1879 of the Act provides for Medicare payment to be made when the beneficiary and the provider, practitioner, or other supplier did not know, and could not reasonably have been expected to know, that Medicare payment would be denied. However, in the prepaid health care context, the Medicare program is insulated from liability in those situations in which the prepaid health care organization assumes financial responsibility for direct payment of an item or service to the provider, practitioner, or other supplier. Although certain prepaid health care organizations may perform the function of determining Medicare coverage, they do not act strictly as an agent of the Medicare program, as do Medicare contractors. Section 1879 was not intended to assign liability in cases in which a health care organization that authorized or furnished noncovered services under contract with Medicare makes direct payment to a subcontractor. We, therefore, conclude that the issue of liability in the prepaid health care context is not governed by section 1879.

There are situations, however, where Medicare enrollees of HCPPs and cost HMOs/CMPs may receive services and have Medicare payment made through Medicare contractors, instead of the prepaid health care organization making direct payment to the provider, practitioner, or other supplier. In these situations, the limitation on liability protection

may apply to the enrollee if services are denied on one of the specific statutory bases described in section II.A. of this Ruling. These situations include the following:

- The HMO/CMP is a cost-reimbursed HMO with a contract under section 1876 of the Act, and the service in question is a provider service which, although it is being arranged for through the HMO/CMP, is a service that the HMO/CMP has opted to have paid by a Medicare contractor under the provisions of section 1876(h)(2)(A);
- The service is one that a Medicare enrollee of an HCPP or a cost HMO/CMP chooses to receive "out of plan" (that is, without having arranged for the service through the HMO/CMP), and the service is, therefore, being billed through the Medicare contractor; or
- The provider, practitioner, other supplier, or beneficiary submits a claim for the service through the Medicare contractor as a result of the HCPP or cost HMO/CMP's refusal to pay for the service.

Medicare enrollees of "risk" HMOs/CMPs under section 1876 of the Act are prohibited from having Medicare program payments made through Medicare contractors. For these enrollees, the only program payment is the capitation payable to the HMO/CMP for each enrolled Medicare beneficiary. Therefore, the limitation on liability provision is never extended to enrollees of the "risk" HMOs/CMPs.

#### IV. DETERMINING KNOWLEDGE

For the protection under the limitation on liability provision to be afforded, lack of prior knowledge that Medicare payment for the item or service would be denied must first be established. Two determinations must be made to establish knowledge: (1) Whether and when the beneficiary knew or should have known that Medicare payment for the item or service would be denied, and (2) whether and when the provider, practitioner, or other supplier knew or should have known that Medicare payment for the item or service would likely be denied. The principles for determining knowledge described below apply to determinations of knowledge with respect to denials under section 1879(a) through (g) of the Act for which Medicare payment may be made, as well as to those under section 1879(h) of the Act, for which refunds may be required.

##### A. Criteria For Determining Beneficiary Knowledge

Section 1879(a)(2) of the Act requires that the beneficiary "did not know, and could not reasonably have been expected to know, that payment would not be made\* \* \*," for items or services that are excluded from coverage as not reasonable and necessary or as custodial care, in order for the limitation on liability protection to be afforded. This includes knowledge based on written notice having been provided to the beneficiary, as well as any other means from

which it is determined that the beneficiary knew, or should have known, that payment would not be made.

Our regulations at 42 CFR 411.404 (Criteria for determining that a beneficiary knew that services or items were excluded from coverage as custodial care or as not reasonable and necessary) provide one basis for determining beneficiary knowledge that payment would not be made for items or services that are excluded from coverage as not reasonable and necessary or as custodial care. These regulations provide that a beneficiary will be considered to know, based on written notice, that services or items were excluded from coverage as not reasonable and necessary or as custodial care. Under these regulations, there is a presumption that he or she knew, or could reasonably have been expected to know, that Medicare payment for a service or item would be denied if advance written notice has been given either to the beneficiary or to someone acting on his or her behalf that the items or services were not covered.

In accordance with § 411.404, a written notice of Medicare denial of payment must contain sufficient information to enable the beneficiary to understand the basis for the denial. Such notice constitutes sufficient documentation to show that the beneficiary had prior knowledge of the likelihood of denial of that claim, and of all future claims filed by or on behalf of the beneficiary that involve that same or a similar item or service. In

addition, a written notice of Medicare denial of payment from a Medicare contractor for a previous claim for a particular service or item received by the beneficiary serves as prior written notice for all future claims filed by or on behalf of the beneficiary that involve that same or a similar service or item.

Generally, the required written notice of the likelihood of denial must be furnished to the beneficiary (or the person acting on his or her behalf) by:

- A provider, practitioner, or other supplier before the service or item was furnished.
- The provider, after the Medicare contractor, during the course of the patient's stay, advised the provider that covered care had ceased.
- A provider utilization review committee that, on admission or during the patient's stay, advised that the patient no longer required covered care.
- The Medicare contractor.

While § 411.404 provides criteria for beneficiary knowledge based on written notice, section 1879(a)(2) of the Act specifies only that knowledge must not exist in order to apply the limitation on liability protection. If it is clear and obvious that a beneficiary in fact did know, prior to receiving a service or item, that Medicare payment for that service or item would be denied, the administrative presumption favorable to the beneficiary referred to in

§ 411.404, is rebutted. For example, if the beneficiary admits that he or she had prior knowledge that payment for a service or item would be denied, no further evidence is required; the absence of a written notice is moot.

The failure of any provider, practitioner, or other supplier to furnish to a beneficiary proper advance notice of the likelihood of denial is not sufficient to afford the beneficiary the protection of the limitation on liability provision if the contractor has proof that the beneficiary, nonetheless, had the requisite knowledge that the service would be denied. In any case in which the contractor has such evidence of prior knowledge on the beneficiary's part, the beneficiary must be held liable under the limitation on liability provision.

B. Determining Provider, Practitioner, or Other Supplier Knowledge

1. General

The Medicare contractors determine, based on the information they maintain and/or disseminate to a particular provider, practitioner, or other supplier, whether the provider, practitioner, or other supplier actually had prior knowledge that services or items would likely be denied or whether knowledge reasonably could have been expected. The determination of actual or expected knowledge is based on all the relevant facts pertaining to each particular denial.

2. Criteria For Determining Practitioner and Other Supplier Knowledge

In accordance with 42 CFR 411.406 (Criteria for determining that a provider, practitioner, or other supplier knew that items or services were excluded from coverage as custodial care or as not reasonable and necessary) and § 7300.5 of the Medicare Carriers Manual, evidence that the practitioner or other supplier did, in fact, know or should have known that Medicare would not pay for a service or item includes:

- A Medicare contractor's prior written notice to the practitioner or other supplier of Medicare denial of payment for similar or reasonably comparable services or items;
- Our general notices to the medical community of Medicare payment denial of services and items under all or certain circumstances. (Our notices include, but are not limited to, manual instructions, bulletins, carriers' written guides, and directives); and
- Provision of the services and items was inconsistent with acceptable standards of practice in the local medical community (refer to section V. of this Ruling).

If any of the circumstances described above exists, a practitioner or other supplier is held to have knowledge.

The practitioner or other supplier is presumed liable for denied services or items at the initial determination, with one exception. If a practitioner or other supplier

gives the beneficiary proper written advance notice that Medicare will likely deny payment for the service or item to be furnished, and so documents the claim, the beneficiary is held liable for the denied services or items at the initial determination. The advance notice must clearly identify the particular service or item, must state that the practitioner or other supplier believes Medicare is likely to deny payment as not reasonable and necessary for the particular service or item, and must give the basis for the practitioner or other supplier's belief that Medicare is likely to deny payment for the service or item, in order to protect the practitioner or other supplier from liability. The beneficiary must be told why the practitioner or supplier is predicting Medicare denial of payment so that the beneficiary can make an informed decision whether to receive the service or item and to pay for it out-of-pocket. Such a notice constitutes proof that the beneficiary had prior knowledge that Medicare payment would be denied for the service or item in question.

In our program instructions (Medicare Carriers Manual § 7300.5(A)), we suggest that the practitioner or supplier have the beneficiary sign the agreement. If a beneficiary's signature is absent, in case of a dispute as to the agreement, the beneficiary's allegations regarding the notice will be given credence.

In summary, if the practitioner or other supplier can show that (1) the beneficiary received proper written advance notice, or (2) the practitioner or other supplier did not know, and could not reasonably have been expected to know, that Medicare would not pay for the service or item, then, absent evidence to the contrary, the medical review entity (in this case the carrier) must find that the practitioner or other supplier is not liable.

### 3. Criteria For Determining Provider Knowledge

#### (a) Favorable Presumption

##### (1) Background

Administrative presumptions ("favorable presumptions") are used for certain categories of providers in determining whether a provider had prior knowledge that Medicare payment for services or items would be denied. We established favorable presumptions in July 1973 because, when the Congress passed the limitation on liability provisions in section 1879 of the Act (section 213 of the Social Security Amendments of 1972, Public Law 92-603), providers were not as knowledgeable about Medicare coverage rules as they later became. In addition, written guidelines were not as explicit as they are now. Therefore, we developed formulas, using statistical denial rate criteria, that allowed providers who usually made correct coverage determinations to be paid for their few incorrect coverage determinations under the presumption that they did not have prior knowledge.

that Medicare payment for the services or items would be denied.

The basis for applying the favorable presumption mechanism, based on the statistical denial rate criteria, was established in our regulations at 42 CFR 405.195 and 405.196. These regulations specified, in part, that a favorable presumption would be allowed if we found that, on the basis of bills submitted, the provider effectively distinguished between cases in which the services or items furnished by the provider were covered under Medicare and cases in which they were excluded from coverage. The favorable presumption mechanism applied from July 1973 until February 1986 to hospitals, SNFs, and home health agencies (HHAs).

On February 21, 1986, we published a final rule in the Federal Register, 51 FR 6222, which added a new 42 CFR 405.336 and removed 42 CFR 405.195 and 405.196. These changes to the regulations revised the way we applied limitation on liability for providers and removed the administrative mechanism of favorable presumption in determining whether a hospital, SNF, or HHA should be held liable for furnishing a service or item for which Medicare payment is denied.

In April 1986, sections 9126(c) and 9205 of the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA), Public Law 99-272, reinstated the use of a

favorable presumption for SNFs (including SNF swing beds) and HHAs, but not for hospitals. Under COBRA, a statistical denial rate criterion remained in effect, which was to be applied in the same manner as under the regulations in effect as of July 1, 1985 (42 CFR 405.195 and 405.196).

In October 1986, section 9305(f) of the Omnibus Budget Reconciliation Act of 1986 (OBRA '86), Public Law 99-509, extended the favorable presumption mechanism to the hospice program. Section 9305(g) of OBRA '86 extended the limitation on liability provision to HHA denials if Medicare payment for home health services a beneficiary received is denied because the beneficiary was not "homebound" or did not require "intermittent skilled nursing care" (as required by sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act). This provision was applicable only to services furnished from July 1, 1987, to October 1, 1989 (section 9305(g)(3) of OBRA '86).

#### (2) Extended Application of Favorable Presumptions

Under statutory provisions, favorable presumptions were extended to apply to HHAs, hospices, and SNFs (including SNF swing beds). The following provisions of the Omnibus Budget Reconciliation Act of 1990 (OBRA '90) extended the application of favorable presumptions until December 31, 1995:

- Section 4008(a)(1) amended section 9126(c) of COBRA for SNFs (including SNF swing beds);

- Section 4008(a)(2) amended section 9305(f) of OBRA '86 for hospices; and
- Section 4207(b)(3) amended section 9305(g) of OBRA '86 for claims for home health services that are denied because the beneficiary was not "homebound" or did not require "intermittent skilled nursing care" (as required by sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act).

(OBRA '90 inadvertently omitted a favorable presumption extension for HHA medical necessity denials by failing to amend section 9205 of COBRA. Therefore, we issued a Program Memorandum (Transmittal No. AB-91-6, July 1991) that administratively extended the HHAs' favorable presumption for medical necessity denials until section 4207(b)(3) of OBRA '90 could be appropriately amended. Section 158(b) of the Social Security Act Amendments of 1994 made this amendment.)

**(3) Criteria For Determining If an HHA, SNF, or Hospice Merits a Favorable Presumption**

As a means of determining whether an HHA, SNF, or hospice merits a favorable presumption, we established and implemented two statistical formulas that provide a measure of the SNF's, HHA's, or hospice's accuracy in assessing whether services and items are covered or noncovered, in accordance with the regulations that existed under 42 CFR 405.195 and 405.196. The first formula calculates the "denial rate," which is a quarterly measurement used to

indicate whether the SNF, HHA, or hospice can generally make correct judgments concerning the coverage of services and items. Denial of very few claims billed as covered is held to demonstrate a provider's ability to make correct coverage assessments under most circumstances. Thus, when a provider does not exceed the denial rate established under COBRA (5 percent of claims submitted for SNFs (including SNF swing beds) and 2.5 percent of claims submitted for HHAs and hospices), a favorable presumption is employed.

The second formula calculates the demand bill "reversal rate," which is a quarterly measurement used to indicate whether the SNF, HHA, or hospice can generally make correct judgments concerning the noncoverage of services and items. A demand bill is a claim for services or items that the provider believes are not covered but which the provider must submit at the demand of the beneficiary or the beneficiary's representative. If the Medicare contractor determines that one or more services or items on such a claim actually do qualify for Medicare payment, the provider's assessment that the service or item is not covered is reversed. Like the denial rate, reversal of very few claims billed as noncovered is held to demonstrate a provider's ability to make correct noncoverage judgments under most circumstances. Thus, when a provider does not exceed the established reversal rate criterion (for SNFs (including SNF swing beds), less than 20 reversals out of

100 or fewer demand bills submitted, or no more than 20 percent if more than 100 demand bills are submitted; for HHAs and hospices, less than 10 reversals out of 100 or fewer demand bills submitted, or no more than 10 percent if more than 100 demand bills are submitted), a favorable presumption is employed.

As long as an SNF, HHA, or hospice remains within both the denial rate threshold and the demand bill reversal rate threshold, all of its denied claims will be processed as if the provider had no prior knowledge that the claims would be denied. However, such a favorable presumption is rebutted and no Medicare payment will be made if it is clear and obvious that the provider knew that particular services or items would be denied (see section IV.B.3.(b) of this Ruling).

We note that a favorable presumption can be employed for purposes of determining a provider's limitation on liability under section 1879 only during a prepayment review of the claim. A favorable presumption amounts to an automatic decision that a provider did not have knowledge that payment would be denied, without a further review of the case to see if there is evidence to the contrary. Therefore, there is no longer a need for a presumption when a postpayment audit review is conducted, because the claim is being reviewed and the reviewer will know, based on the specific facts of the case, whether the provider had

knowledge that payment would be denied on the basis that services and items were not reasonable and necessary.

Therefore, a favorable presumption is not relevant for purposes of a postpayment audit review.

In addition, for appeal purposes, the existence/non-existence of a favorable presumption is determined based on a provider's statistical standing at the time the initial claim determination is made, not at the time of the appeal hearing.

(b) When a Provider Is Always Considered To Have Prior Knowledge

No Medicare payment will be made to any provider for any claim if previous notification was given or if for any other reason the provider clearly should have known that the claim would be denied. This includes providers that have a favorable presumption, since the presumption is rebutted where there is clear and obvious evidence that the provider knew or should have known that the services or items at issue would be denied.

Sections 9126(c) and 9205 of COBRA and section 9305(f) of OBRA '86, which reinstated the use of a favorable presumption, require application of the presumption in the manner provided in regulations in effect as of July 1, 1985 (42 CFR 405.195 and 405.196). Section 405.195(a) explicitly provided for a rebuttable presumption. General legal principles provide that a rebuttable (or "disputable")

presumption controls unless and until it is invalidated by proof of evidence contrary to the presumption. If evidence contrary to the presumption is found, the presumption disappears and the case stands upon the facts and the reasonable inferences to be drawn therefrom. Therefore, in all cases in which there is evidence that a provider had knowledge or should have had knowledge that services or items would be denied, the favorable presumption is rebutted.

Criteria for determining whether a provider had knowledge or should have had knowledge that services or items would be denied are in regulations at 42 CFR 411.406 and in § 3439.B. through 3439.G. of the Medicare Intermediary Manual. These sources cite various forms and methods of notification that provide sufficient evidence that the provider knew or should have known that the services or items would be denied. Such notices are sufficient notice for all subsequent claims involving that same service or item under similar or reasonably comparable conditions. In general, notification often is provided by one of the following sources:

- The provider's utilization review committee informed the provider in writing that the services were not covered;
- The provider previously submitted a no-payment claim (i.e., a pro forma filing in which no payment is sought, rather, only a formal payment denial determination is

requested), or submitted a claim for Medicare payment only at the request of the beneficiary;

- The provider issued a written notice of the likelihood of Medicare payment denial for a service or item to the beneficiary;

- We have issued manuals, bulletins, memoranda, etc., advising providers of the noncoverage of a particular service or category of services;

- A Medicare contractor previously issued a written notice to the provider that Medicare payment for a particular service or item is denied. This also includes notification of PRO screening criteria specific to the condition of the beneficiary for whom the furnished services are at issue and of medical procedures subject to preadmission review by the PRO;

- The provider was previously notified by telephone and/or in writing that care is not covered or that covered care has ended; or

- A general bulletin or newsletter was issued to providers advising that a specific service or item is not considered reasonable and necessary.

The provider is accountable for information contained in the patient's medical records, such as the patient's medical chart, attending physicians' notes, or similar records, since these are provider records. Evidence based upon medical records, such as that described in the

following list, clearly indicates knowledge that Medicare payment for services or items would be denied:

- A physician clearly indicated in the patient's medical record that the patient no longer needed the services or the level of care provided;
- The physician indicated the patient could be discharged; or
- The attending physician refused to certify or recertify the patient's need for a particular level of care covered by Medicare because he/she determined that the patient does not require a covered level of care.

#### **V. ACCEPTABLE STANDARDS OF PRACTICE--APPLICATION**

In situations in which services or items furnished do not meet locally acceptable standards of practice, the provider, practitioner, or other supplier is considered to have known that Medicare payment for the services or items would be denied. Providers, practitioners, and other suppliers are always responsible for knowing locally acceptable standards of practice; their local licensure is premised on the assumption that they have such knowledge. Medicare payment to providers, practitioners, or other suppliers is premised on the presumption that they have such knowledge, as evidenced by their licensure. No other evidence of knowledge of local medical standards of practice is necessary.

Medicare contractors, in determining what "acceptable standards of practice" exist within the local medical community, rely on published medical literature, a consensus of expert medical opinion, and consultations with their medical staff, medical associations, including local medical societies, and other health experts. "Published medical literature" refers generally to scientific data or research studies that have been published in peer-reviewed medical journals or other specialty journals that are well recognized by the medical profession, such as the "New England Journal of Medicine" and the "Journal of the American Medical Association." By way of example, consensus of expert medical opinion might include recommendations that are derived from technology assessment processes conducted by organizations such as the Blue Cross and Blue Shield Association or the American College of Physicians, or findings published by the Institute of Medicine.

#### **VI. FRAUD AND ABUSE--APPLICATION**

Generally, the protection under the limitation on liability provision cannot be afforded to providers, practitioners, or other suppliers if a formal finding of fraud or abuse has been made with regard to a provider's, practitioner's, or other supplier's billing practices. In cases in which a formal finding of fraud or abuse is made, an immediate finding of liability for the provider, practitioner, or other supplier results.

VII. PAYMENT UNDER LIMITATION ON LIABILITY

A. Beneficiary Is Determined To Be Not Liable

For claims denied solely on the basis of one of the provisions listed in section II.A of this Ruling and it has been determined that the beneficiary did not know and could not reasonably have been expected to know that the service or item would be denied, the following are the effects:

- Under section 1879(a)(2) of the Act and the accompanying regulations at 42 CFR 411.400(a)(2), the Medicare program must make payment when the provider, practitioner, or other supplier did not know and could not reasonably have been expected to know that the services or items would be denied. In these instances, the usual deductible and coinsurance amounts apply. The number of days or visits paid for under the limitation on liability provision is charged to the beneficiary's utilization record. Medicare payment may also be made under section 1154(a)(2)(B) of the Act and 42 CFR 411.400(b)(2) for a 1-day "grace period" after the date of notice to the provider or to the beneficiary, whichever is earlier, if additional time is needed to arrange for post-discharge care. If it is determined thereafter by a PRO or the Medicare contractor that even more time is required in order to arrange post-discharge care, 1 additional "grace period" day is paid. Initial approval of 2 or more "grace period" days is not permitted. The "grace period" is applicable

only if circumstances would have permitted Medicare program payment under section 1879(a)(1) and (2) of the Act and 42 CFR 411.400(b)(2), that is, protection under the limitation on liability provision was afforded both to the beneficiary and the provider;

- Under section 1879(b) of the Act and 42 CFR 411.402, Medicare does not make payment when it is determined that the provider, practitioner, or other supplier had prior knowledge that Medicare would deny payment for services or items or could reasonably have been expected to have had this knowledge. In these instances, the beneficiary is not responsible for paying the deductible and coinsurance charges related to the denied claim and the beneficiary's Medicare utilization record is not charged for the services and items furnished, effective for all services or items furnished on or after January 1, 1988.

In addition, under section 1879(b) and 42 CFR 411.402 et seq., if the provider, practitioner, or other supplier is considered to be liable and requests and receives payment from the beneficiary or any person(s) who assumed financial responsibility for payment of the beneficiary's expenses, the Medicare program indemnifies the beneficiary or other person(s) for any amounts paid by the beneficiary. This includes any deductible or coinsurance charges paid by or on behalf of the beneficiary. Further, these indemnification

payments are considered an overpayment to the provider, practitioner, or other supplier.

**B. Beneficiary Is Determined To Be Liable**

Under section 1879(c) of the Act and 42 CFR 411.404, the beneficiary is held to be liable when it is determined that he or she had prior knowledge that Medicare payment for the service or item would be denied or could reasonably have been expected to have had such knowledge. In these instances, the beneficiary is held responsible for expenses incurred for services or items for which Medicare payment is denied, regardless of whether the provider, practitioner, or other supplier had knowledge. The Medicare program makes no payment to the beneficiary, provider, practitioner, or other supplier.

**VIII. APPEALS**

**A. Beneficiary's Right To Appeal**

If the Medicare contractor determines that the beneficiary knew or could reasonably have been expected to know that Medicare payment for the services or items furnished would be denied, the beneficiary has appeal rights for both the determination holding him or her liable for the cost of the denied services or items and the substantive coverage determination. In addition, if Medicare pays the claim in accordance with section 1879 of the Act (that is, the Medicare contractor determines that neither the beneficiary nor the provider, practitioner, or other

supplier knew or could reasonably have been expected to know that the services or items would be denied), the beneficiary may still appeal the coverage determination.

B. Provider's Right to Appeal

If the Medicare contractor finds (1) that the beneficiary or the provider (or both) knew or could reasonably have been expected to know that Medicare payment for the services or items furnished would be denied, or (2) that the beneficiary did not know and could not reasonably have been expected to know that Medicare payment for the services or items furnished would be denied, and the beneficiary chooses not to exercise his or her appeal rights, the provider may appeal both the coverage and the liability determinations. However, if Medicare pays the claim in accordance with section 1879 of the Act, the provider may not appeal the coverage determination.

C. Practitioner's and Other Supplier's Right to Appeal

When it is determined by the Medicare contractor that a practitioner who accepts assignment or an other supplier who accepts assignment knew or could reasonably have been expected to know that Medicare payment for the services or items furnished would be denied, the practitioner or other supplier may appeal both the coverage and the liability determinations. In addition, if Medicare pays the claim in accordance with section 1879 of the Act, the practitioner

who accepts assignment or the other supplier who accepts assignment may still appeal the coverage determination.

D. PRO Determinations

Under title XI of the Act, when a PRO determines that a provider or practitioner is liable for payment of denied services and items furnished a beneficiary, the provider or practitioner may appeal the coverage determination and/or the liability determination only through the reconsideration or review level of appeal. At any appeal beyond the reconsideration or review level, the provider or practitioner may challenge only the PRO's liability determination, not the substantive coverage determination.

Medicare Part A limitation on liability determinations are governed by procedures in 42 CFR part 405, subpart G. Medicare Part B limitation on liability determinations are governed by procedures in 42 CFR part 405, subpart H, and 42 CFR part 473. When the PRO makes a limitation on liability determination on a Part B claim, which is governed by subpart H of 42 CFR part 405, either the PRO or the carrier may conduct the fair hearing. Part B ALJ hearings and Appeals Council review are conducted pursuant to the procedures outlined in HCFA and SSA's Federal Register notice of June 1, 1988, 53 FR 20023 (June 1, 1988), unless superseded by subsequent regulations.

#### IX. EFFECTIVE DATE

This Ruling is effective December 31, 1995.

Dated: 12/22/95

  
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Bruce C. Vladeck,  
Administrator,  
Health Care Financing  
Administration



How to use these separators

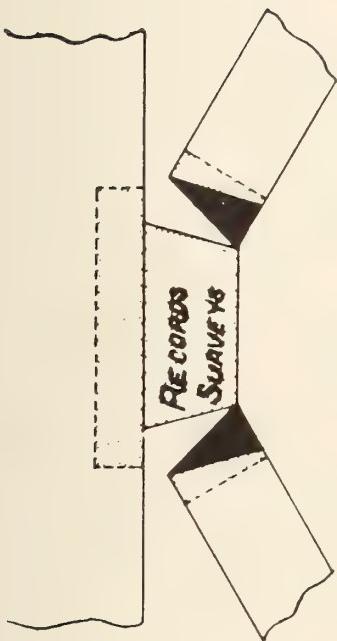
Look for your reference letter. The far left column designated "TAB" will indicate proper tab position for that number or letter. Cut off and discard all tabs except the one you wish to retain. Example: Position number "10" would be found behind the fourth tab. Position letter "C" would be found behind the third tab.

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THIRD	100	93	86	79	72	65	58	51	44	37	30	23	16	9	2
FOURTH	94	87	80	73	66	59	52	45	38	31	24	17	10	3	
FIFTH	95	88	81	74	67	60	53	46	39	32	25	18	11	4	
SIXTH	96	89	82	75	68	61	54	47	40	33	26	19	12	5	
SEVENTH	97	90	83	76	69	62	55	48	41	34	27	20	13	6	





# HCFA Rulings

Department of Health  
and Human Services

Health Care Financing  
Administration

Ruling No

HCFAR-94-1

Date April 1994

HCFA Rulings are decisions of the Administrator that serve as precedent final opinions and orders and statements of policy and interpretation. They provide clarification and interpretation of complex or ambiguous statutory or regulatory provisions relating to Medicare, Medicaid, Utilization and Quality Control Peer Review, and related matters.

HCFA Rulings are binding on all HCFA components, the Provider Reimbursement Review Board and Administrative Law Judges who hear Medicare appeals. These decisions promote consistency in interpretation of policy and adjudication of disputes.

This Ruling announces the Health Care Financing Administration's policy regarding Medicare payment if an entity required or responsible to pay primary benefits is bankrupt or insolvent. Under these circumstances, HCFA will not make Medicare conditional primary payments. Also, HCFA will not make Medicare secondary payments in advance, but will determine the amount of Medicare secondary payments after the conclusion of the bankruptcy or insolvency proceedings.



**MEDICARE PROGRAM****Hospital Insurance Benefits (Part A) Program and Supplementary Medical Insurance (Part B) Program****Policy Regarding Medicare Payments in the Event a Primary Payer Is Bankrupt or Insolvent**

**PURPOSE:** This Ruling sets forth the Health Care Financing Administration's (HCFA's) policy regarding Medicare payment if an entity required or responsible to pay primary benefits is bankrupt or insolvent and cannot make the contracted primary payment. This Ruling provides notice that Medicare will not make conditional primary payments nor will Medicare make secondary payments in advance in the event that a primary payer fails to pay benefits because of bankruptcy or insolvency. This decision is consistent with section 1862(b)(2)(A) of the Social Security Act (the Act), which states that payment may not be made when payment has been or can reasonably be expected to be made, by a primary payer. In the case of a bankrupt or insolvent primary payer, this provision would apply to the entity or entities (for example, the State guaranty fund, reinsurer, bankruptcy trustee, receiver, or estate) that are responsible for settling and/or paying the outstanding debts of the bankrupt or insolvent primary payer. Section 1862(b)(2)(B)(i) of the Act authorizes

conditional payments, with the understanding that the Trust Fund will be reimbursed if it is determined that payment has been made or could reasonably be expected to be made by a third party payer. Therefore, the Medicare program is under no obligation to make conditional payments.

CITATIONS: Section 1862(b)(2) of the Social Security Act (42 U.S.C. 1395y(b)(2)); 42 CFR §§ 411.20, 411.24(e) and 424.44.

PERTINENT HISTORY: A Medicare beneficiary died after incurring medical expenses of approximately \$39,000 in connection with her terminal illness. Before her death, the providers that furnished her services had filed Medicare claims under their Medicare provider agreements, and the physicians and other suppliers that furnished her services had filed Medicare claims on an assignment-related basis. The Medicare contractors denied the Medicare claims of the providers, and physicians and other suppliers because a private health plan, the XYZ Trust, was her primary coverage. The providers, and physicians and other suppliers then filed claims with the Trust. Shortly after the beneficiary's death, however, the Trust became insolvent and was placed in the hands of a receiver, the State Commissioner of Insurance. In this particular State (Georgia), State law requires the receiver to give potential claimants, including those who had already filed claims with the Trust, written notice

of the right to file claims with the receiver. A period of 6 months must then be allowed for the claims to be filed. Thereafter, it takes a year and a half or more for the receiver to marshal the assets of the Trust and to process the claims. The receiver may then be able to make only a fractional payment, perhaps as little as 10 cents for each dollar value of the claims. During the liquidation process, however, the providers, and physicians and other suppliers have filed claims with the beneficiary's estate and are dunning the beneficiary's husband for payment.

The questions being raised in this case are as follows:

- Will Medicare make a conditional primary payment if a third party payer fails to pay primary benefits in accordance with its contract because the company has become bankrupt or insolvent?
- In bankruptcy or insolvency cases, will Medicare make a secondary payment before the liquidation process is completed?
- After the bankruptcy or insolvency has been resolved, how will Medicare secondary payments, if any, be determined?

HCFA's policy in bankruptcy and insolvency situations is that--  
(1) Medicare will not make any payment until the liquidation process is completed; and (2) Medicare will not make a secondary

payment in advance of a determination of the appropriate primary payment. HCFA's policy is consistent with the provisions in section 1862(b)(2)(A) of the Act and 42 CFR §411.20, which provide that Medicare payment may not be made to the extent that payment has been made, or can reasonably be expected to be made, by a primary payer. Section 1862(b)(2)(A) defines a "primary plan" (that is, the primary payer) to mean a group health plan or large group health plan.

When an entity required or responsible to pay primary benefits becomes bankrupt or insolvent, Medicare payment may not be made to the extent that payment can reasonably be expected to be made by--(1) the bankrupt or insolvent entity required or responsible to pay; or (2) the entity or entities responsible for settling and/or paying the outstanding debts of the bankrupt or insolvent entity, as determined in the liquidation process. (Entities required to pay or responsible for paying primary benefits include employers, insurance carriers, plans, or programs, and third party administrators (42 CFR § 411.24(e))). Whether the entity is able to make a primary payment, and the amount of the primary payment, is not determined until the end of the liquidation process.

Section 1862(b)(2)(B)(i) of the Act provides that all Medicare payments are conditioned on reimbursement to the appropriate

Medicare Trust Fund when notice or other information is received that payment for the item or service has been or could be made by a primary payer. The law, however, does not obligate Medicare to make conditional payments. We have determined that conditional primary payments shall not be made in cases involving bankrupt or insolvent entities required or responsible to pay primary benefits. The administrative procedures that would be involved in tracking bankruptcy or insolvency cases through the lengthy liquidation process would be extremely costly, burdensome, and time-consuming. Further, there is no certainty that Medicare would be able to recover any payment that may be due it at the end of the process. Thus, it would not be appropriate for Medicare to make conditional payments in cases involving bankrupt or insolvent entities that are required or responsible to pay primary.

Participating providers, and physicians and other suppliers that have accepted assignment, may not during the liquidation process collect or seek to collect from the beneficiary, or the beneficiary's estate, charges for Medicare-covered services. Under the terms of the Medicare provider agreement and the terms of the Medicare assignment, the providers, and physicians and other suppliers may bill the beneficiary (or the beneficiary's estate) only to establish a legal claim for future collection of

charges, and not for purposes of currently collecting charges from the beneficiary or the beneficiary's estate.

Regarding Medicare secondary payments before the conclusion of the liquidation process, there is no way to determine the proper amount of the secondary payment since there would not be a determination of what funds are available from the bankrupt or insolvent entity. Also, there would be no Explanation of Benefits or similar statement available upon which to base a Medicare secondary payment. Therefore, any estimates for payment made in advance would be speculative.

A Medicare secondary payment may be made after the conclusion of the liquidation process if--(1) the payment made on behalf of the bankrupt or insolvent entity responsible for paying primary benefits is less than the amount of the charge and less than the amount Medicare would have paid as the primary payer; and (2) the provider, and physician or other supplier is not required to accept that payment as full discharge of the liability of the beneficiary (or the estate) for the bill.

At the conclusion of the liquidation process, the amount of the Medicare secondary payment will be computed by the Medicare contractor based on the amount of the primary payer's liability, as determined by the receiver. To determine the amount of

Medicare secondary payment, the Medicare contractor must obtain specific information from the receiver regarding the terms of the payments made by the receiver on behalf of the primary payer.

One possibility is that the Medicare secondary payment may be computed based on the amount the receiver pays on behalf of the bankrupt or insolvent entity as partial satisfaction of the entity's liability for primary payment. In effect, this would mean that the Medicare secondary payment would make up for the liability of the primary payer that was not satisfied because of lack of funds.

Example: A participating physician furnishes a service for which the approved charges of the primary payer and of Medicare are \$100 and \$90, respectively. The primary payer would normally pay 80 percent of \$100, or \$80, and Medicare would make a secondary payment of \$100 minus \$80, or \$20. However, the primary payer is bankrupt and, after a long delay, its receiver pays the physician only \$32. Medicare pays the physician \$100 minus \$32, or \$68, which is \$48 more than its normal liability (that is, \$68 minus \$20).

A second possibility is that the fractional payment made by the receiver must be accepted as full discharge of the amount the primary payer would have been obligated to pay were it not bankrupt or insolvent. In the above example, the receiver might

determine that the \$32 it pays fully discharges the liability of the primary payer for the \$80 the primary payer would have paid if it were solvent. In this situation, the Medicare secondary payment amount may be the amount payable had the receiver paid the full primary payment, that is, Medicare would pay only \$100 minus \$80, or \$20.

The third possibility is that the provider, and physician or other supplier may be required to accept the fractional payment as full discharge of the entire bill. In the above example, the receiver might determine that the physician must accept the \$32 it pays as full discharge of the liability of the estate for \$100. In this case, Medicare would make no secondary payment.

Once the liquidation process has been completed, the providers, and physicians or other suppliers can file Medicare secondary claims. The time limit on filing the claims will be the later of the following: (1) the usual time limit specified in regulations for filing Medicare claims (that is, on or before December 31 of the calendar year following the year in which the services were furnished if the services were furnished during the first 9 months of a calendar year, or on or before December 31 of the second calendar year following the year in which the services were furnished if the services were furnished during the last 3 months of the calendar year (42 CFR § 424.44(a))); or (2) the

last day of the 6th calendar month following the month of the written notice by the bankrupt or insolvent entity to the provider, and physician or other supplier of the primary benefits payable. After the claims have been filed, the Medicare contractor will make the appropriate Medicare secondary payment.

Participating providers, and physicians and other suppliers that have accepted assignment should file claims with a receiver as soon as possible. The receiver will determine the payments that can be made on behalf of the bankrupt or insolvent entity. The providers, and physicians and other suppliers will receive any available primary payment from the receiver, and can then file Medicare claims to obtain the appropriate secondary payments, if any. After the Medicare secondary claims have been processed, any remaining liability (for example, deductibles, coinsurance, and payment for non-covered services) of the beneficiary (or of a deceased beneficiary's estate) can be determined and pursued by the providers, and physicians and other suppliers. However, remaining liability, if any, cannot be pursued if a receiver orders that the allocated fractional payment must be accepted as full discharge of the entire bill.

Although the factual situations described in this Ruling have involved only claims from providers, and physicians and other suppliers who accepted assignment, this Ruling also applies to

claims from beneficiaries and their estates. HCFA will not make Medicare conditional primary payments or Medicare secondary payments to any entity in advance of the conclusion of the applicable bankruptcy or insolvency proceedings.

RULING: It is HCFA's determination that if an entity required or responsible to pay primary benefits becomes bankrupt or insolvent, Medicare will not make conditional primary payments. Further, Medicare will not make a secondary payment in advance of a determination of the appropriate primary payment. A secondary payment may be made after the conclusion of the liquidation process if the payment made on behalf of the bankrupt or insolvent entity responsible for paying primary benefits is less than the amount of the charge and less than the amount Medicare would have paid as the primary payer, and the provider, and physician or other supplier is not required to accept that payment as full discharge of the liability of the beneficiary (or the estate) for the bill. This Ruling is applicable to any entity filing a claim for Medicare benefits, including providers, and physicians and other suppliers, and beneficiaries.

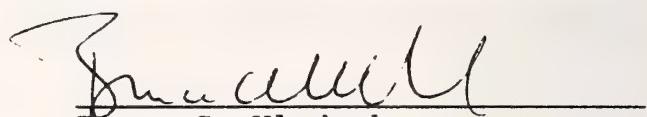
Participating providers, and physicians and other suppliers that have accepted assignment, may not during the liquidation process collect or seek to collect from the beneficiary, or the beneficiary's estate, charges for Medicare-covered services.

Under the terms of the Medicare provider agreement and the terms of the Medicare assignment, providers, and physicians and other suppliers may bill the beneficiary (or the beneficiary's estate) only to establish a legal claim for future collection of charges, and not for purposes of currently collecting charges from the beneficiary or the beneficiary's estate.

EFFECTIVE DATE

This Ruling is effective April 18, 1994.

Dated: April 18, 1994

  
Bruce C. Vladeck,  
Administrator, Health Care  
Financing Administration.

# HCFA Rulings

Department of Health  
and Human Services

Health Care Financing  
Administration

Ruling No

HCFAR-94-1

Date April 1994

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This Ruling announces the Health Care Financing Administration's policy regarding Medicare payment if an entity required or responsible to pay primary benefits is bankrupt or insolvent. Under these circumstances, HCFA will not make Medicare conditional primary payments. Also, HCFA will not make Medicare secondary payments in advance, but will determine the amount of Medicare secondary payments after the conclusion of the bankruptcy or insolvency proceedings.



**MEDICARE PROGRAM****Hospital Insurance Benefits (Part A) Program and Supplementary Medical Insurance (Part B) Program****Policy Regarding Medicare Payments in the Event a Primary Payer Is Bankrupt or Insolvent**

**PURPOSE:** This Ruling sets forth the Health Care Financing Administration's (HCFA's) policy regarding Medicare payment if an entity required or responsible to pay primary benefits is bankrupt or insolvent and cannot make the contracted primary payment. This Ruling provides notice that Medicare will not make conditional primary payments nor will Medicare make secondary payments in advance in the event that a primary payer fails to pay benefits because of bankruptcy or insolvency. This decision is consistent with section 1862(b)(2)(A) of the Social Security Act (the Act), which states that payment may not be made when payment has been or can reasonably be expected to be made, by a primary payer. In the case of a bankrupt or insolvent primary payer, this provision would apply to the entity or entities (for example, the State guaranty fund, reinsurer, bankruptcy trustee, receiver, or estate) that are responsible for settling and/or paying the outstanding debts of the bankrupt or insolvent primary payer. Section 1862(b)(2)(B)(i) of the Act authorizes

conditional payments, with the understanding that the Trust Fund will be reimbursed if it is determined that payment has been made or could reasonably be expected to be made by a third party payer. Therefore, the Medicare program is under no obligation to make conditional payments.

CITATIONS: Section 1862(b)(2) of the Social Security Act (42 U.S.C. 1395y(b)(2)); 42 CFR §§ 411.20, 411.24(e) and 424.44.

PERTINENT HISTORY: A Medicare beneficiary died after incurring medical expenses of approximately \$39,000 in connection with her terminal illness. Before her death, the providers that furnished her services had filed Medicare claims under their Medicare provider agreements, and the physicians and other suppliers that furnished her services had filed Medicare claims on an assignment-related basis. The Medicare contractors denied the Medicare claims of the providers, and physicians and other suppliers because a private health plan, the XYZ Trust, was her primary coverage. The providers, and physicians and other suppliers then filed claims with the Trust. Shortly after the beneficiary's death, however, the Trust became insolvent and was placed in the hands of a receiver, the State Commissioner of Insurance. In this particular State (Georgia), State law requires the receiver to give potential claimants, including those who had already filed claims with the Trust, written notice

of the right to file claims with the receiver. A period of 6 months must then be allowed for the claims to be filed. Thereafter, it takes a year and a half or more for the receiver to marshal the assets of the Trust and to process the claims. The receiver may then be able to make only a fractional payment, perhaps as little as 10 cents for each dollar value of the claims. During the liquidation process, however, the providers, and physicians and other suppliers have filed claims with the beneficiary's estate and are dunning the beneficiary's husband for payment.

The questions being raised in this case are as follows:

- o Will Medicare make a conditional primary payment if a third party payer fails to pay primary benefits in accordance with its contract because the company has become bankrupt or insolvent?
- o In bankruptcy or insolvency cases, will Medicare make a secondary payment before the liquidation process is completed?
- o After the bankruptcy or insolvency has been resolved, how will Medicare secondary payments, if any, be determined?

HCFA's policy in bankruptcy and insolvency situations is that--  
(1) Medicare will not make any payment until the liquidation process is completed; and (2) Medicare will not make a secondary

payment in advance of a determination of the appropriate primary payment. HCFA's policy is consistent with the provisions in section 1862(b)(2)(A) of the Act and 42 CFR §411.20, which provide that Medicare payment may not be made to the extent that payment has been made, or can reasonably be expected to be made, by a primary payer. Section 1862(b)(2)(A) defines a "primary plan" (that is, the primary payer) to mean a group health plan or large group health plan.

When an entity required or responsible to pay primary benefits becomes bankrupt or insolvent, Medicare payment may not be made to the extent that payment can reasonably be expected to be made by--(1) the bankrupt or insolvent entity required or responsible to pay; or (2) the entity or entities responsible for settling and/or paying the outstanding debts of the bankrupt or insolvent entity, as determined in the liquidation process. (Entities required to pay or responsible for paying primary benefits include employers, insurance carriers, plans, or programs, and third party administrators (42 CFR § 411.24(e))). Whether the entity is able to make a primary payment, and the amount of the primary payment, is not determined until the end of the liquidation process.

Section 1862(b)(2)(B)(i) of the Act provides that all Medicare payments are conditioned on reimbursement to the appropriate

Medicare Trust Fund when notice or other information is received that payment for the item or service has been or could be made by a primary payer. The law, however, does not obligate Medicare to make conditional payments. We have determined that conditional primary payments shall not be made in cases involving bankrupt or insolvent entities required or responsible to pay primary benefits. The administrative procedures that would be involved in tracking bankruptcy or insolvency cases through the lengthy liquidation process would be extremely costly, burdensome, and time-consuming. Further, there is no certainty that Medicare would be able to recover any payment that may be due it at the end of the process. Thus, it would not be appropriate for Medicare to make conditional payments in cases involving bankrupt or insolvent entities that are required or responsible to pay primary.

Participating providers, and physicians and other suppliers that have accepted assignment, may not during the liquidation process collect or seek to collect from the beneficiary, or the beneficiary's estate, charges for Medicare-covered services. Under the terms of the Medicare provider agreement and the terms of the Medicare assignment, the providers, and physicians and other suppliers may bill the beneficiary (or the beneficiary's estate) only to establish a legal claim for future collection of

charges, and not for purposes of currently collecting charges from the beneficiary or the beneficiary's estate.

Regarding Medicare secondary payments before the conclusion of the liquidation process, there is no way to determine the proper amount of the secondary payment since there would not be a determination of what funds are available from the bankrupt or insolvent entity. Also, there would be no Explanation of Benefits or similar statement available upon which to base a Medicare secondary payment. Therefore, any estimates for payment made in advance would be speculative.

A Medicare secondary payment may be made after the conclusion of the liquidation process if--(1) the payment made on behalf of the bankrupt or insolvent entity responsible for paying primary benefits is less than the amount of the charge and less than the amount Medicare would have paid as the primary payer; and (2) the provider, and physician or other supplier is not required to accept that payment as full discharge of the liability of the beneficiary (or the estate) for the bill.

At the conclusion of the liquidation process, the amount of the Medicare secondary payment will be computed by the Medicare contractor based on the amount of the primary payer's liability, as determined by the receiver. To determine the amount of

Medicare secondary payment, the Medicare contractor must obtain specific information from the receiver regarding the terms of the payments made by the receiver on behalf of the primary payer.

One possibility is that the Medicare secondary payment may be computed based on the amount the receiver pays on behalf of the bankrupt or insolvent entity as partial satisfaction of the entity's liability for primary payment. In effect, this would mean that the Medicare secondary payment would make up for the liability of the primary payer that was not satisfied because of lack of funds.

Example: A participating physician furnishes a service for which the approved charges of the primary payer and of Medicare are \$100 and \$90, respectively. The primary payer would normally pay 80 percent of \$100, or \$80, and Medicare would make a secondary payment of \$100 minus \$80, or \$20. However, the primary payer is bankrupt and, after a long delay, its receiver pays the physician only \$32. Medicare pays the physician \$100 minus \$32, or \$68, which is \$48 more than its normal liability (that is, \$68 minus \$20).

A second possibility is that the fractional payment made by the receiver must be accepted as full discharge of the amount the primary payer would have been obligated to pay were it not bankrupt or insolvent. In the above example, the receiver might

determine that the \$32 it pays fully discharges the liability of the primary payer for the \$80 the primary payer would have paid if it were solvent. In this situation, the Medicare secondary payment amount may be the amount payable had the receiver paid the full primary payment, that is, Medicare would pay only \$100 minus \$80, or \$20.

The third possibility is that the provider, and physician or other supplier may be required to accept the fractional payment as full discharge of the entire bill. In the above example, the receiver might determine that the physician must accept the \$32 it pays as full discharge of the liability of the estate for \$100. In this case, Medicare would make no secondary payment.

Once the liquidation process has been completed, the providers, and physicians or other suppliers can file Medicare secondary claims. The time limit on filing the claims will be the later of the following: (1) the usual time limit specified in regulations for filing Medicare claims (that is, on or before December 31 of the calendar year following the year in which the services were furnished if the services were furnished during the first 9 months of a calendar year, or on or before December 31 of the second calendar year following the year in which the services were furnished if the services were furnished during the last 3 months of the calendar year (42 CFR § 424.44(a))); or (2) the

last day of the 6th calendar month following the month of the written notice by the bankrupt or insolvent entity to the provider, and physician or other supplier of the primary benefits payable. After the claims have been filed, the Medicare contractor will make the appropriate Medicare secondary payment.

Participating providers, and physicians and other suppliers that have accepted assignment should file claims with a receiver as soon as possible. The receiver will determine the payments that can be made on behalf of the bankrupt or insolvent entity. The providers, and physicians and other suppliers will receive any available primary payment from the receiver, and can then file Medicare claims to obtain the appropriate secondary payments, if any. After the Medicare secondary claims have been processed, any remaining liability (for example, deductibles, coinsurance, and payment for non-covered services) of the beneficiary (or of a deceased beneficiary's estate) can be determined and pursued by the providers, and physicians and other suppliers. However, remaining liability, if any, cannot be pursued if a receiver orders that the allocated fractional payment must be accepted as full discharge of the entire bill.

Although the factual situations described in this Ruling have involved only claims from providers, and physicians and other suppliers who accepted assignment, this Ruling also applies to

claims from beneficiaries and their estates. HCFA will not make Medicare conditional primary payments or Medicare secondary payments to any entity in advance of the conclusion of the applicable bankruptcy or insolvency proceedings.

**RULING:** It is HCFA's determination that if an entity required or responsible to pay primary benefits becomes bankrupt or insolvent, Medicare will not make conditional primary payments. Further, Medicare will not make a secondary payment in advance of a determination of the appropriate primary payment. A secondary payment may be made after the conclusion of the liquidation process if the payment made on behalf of the bankrupt or insolvent entity responsible for paying primary benefits is less than the amount of the charge and less than the amount Medicare would have paid as the primary payer, and the provider, and physician or other supplier is not required to accept that payment as full discharge of the liability of the beneficiary (or the estate) for the bill. This Ruling is applicable to any entity filing a claim for Medicare benefits, including providers, and physicians and other suppliers, and beneficiaries.

Participating providers, and physicians and other suppliers that have accepted assignment, may not during the liquidation process collect or seek to collect from the beneficiary, or the beneficiary's estate, charges for Medicare-covered services.

Under the terms of the Medicare provider agreement and the terms of the Medicare assignment, providers, and physicians and other suppliers may bill the beneficiary (or the beneficiary's estate) only to establish a legal claim for future collection of charges, and not for purposes of currently collecting charges from the beneficiary or the beneficiary's estate.

EFFECTIVE DATE

This Ruling is effective April 18, 1994.

Dated: April 18, 1994

Bruce C. Vladick,  
Administrator, Health Care  
Financing Administration.

# HCFA Rulings

Department of Health  
and Human Services

Health Care Financing  
Administration

Ruling No

HCFAR-94-1

Date April 1994

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RULING: It is HCFA's determination that if an entity required or responsible to pay primary benefits becomes bankrupt or insolvent, Medicare will not make conditional primary payments. Further, Medicare will not make a secondary payment in advance of a determination of the appropriate primary payment. A secondary payment may be made after the conclusion of the liquidation process if the payment made on behalf of the bankrupt or insolvent entity responsible for paying primary benefits is less than the amount of the charge and less than the amount Medicare would have paid as the primary payer, and the provider, and physician or other supplier is not required to accept that payment as full discharge of the liability of the beneficiary (or the estate) for the bill. This Ruling is applicable to any entity filing a claim for Medicare benefits, including providers, and physicians and other suppliers, and beneficiaries.

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EFFECTIVE DATE

This Ruling is effective April 18, 1994.

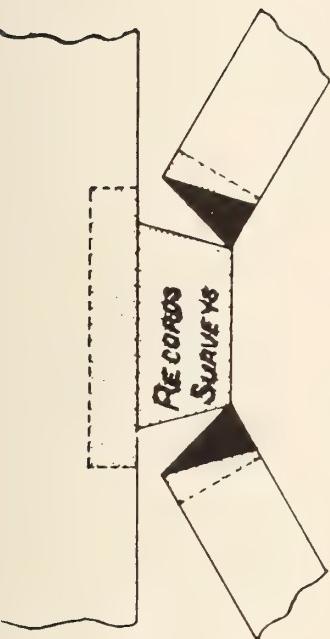
Dated: April 18, 1994

Bruce C. Vladreck  
Bruce C. Vladreck,  
Administrator, Health Care  
Financing Administration.

**How to use these separators**

Look for your reference letter. The far left column designated "TAB" will indicate proper tab position for that number or letter. Cut off and discard all tabs except the one you wish to retain. Example: Position number "10" would be found behind the fourth tab. Position letter "C" would be found behind the third tab.

<b>TAB</b>	(CHOOSE YOUR TAB)			
FIRST	V	O	H	A
SECOND	W	P	I	B
THIRD	X	Q	J	C
FOURTH	Y	R	K	D
FIFTH	Z	S	L	E
SIXTH		T	M	F
SEVENTH	U	N	G	



Recorros  
Survey #

<b>TAB</b>	(CHOOSE YOUR TAB)														
FIRST	98	91	84	77	70	63	56	49	42	35	28	21	14	7	0
SECOND	99	92	85	78	71	64	57	50	43	36	29	22	15	8	1
THIRD	100	93	86	79	72	65	58	51	44	37	30	23	16	9	2
FOURTH		94	87	80	73	66	59	52	45	38	31	24	17	10	3
FIFTH		95	88	81	74	67	60	53	46	39	32	25	18	11	4
SIXTH		96	89	82	75	68	61	54	47	40	33	26	19	12	5
SEVENTH		97	90	83	76	69	62	55	48	41	34	27	20	13	6



# HCFA Rulings

Department of Health  
and Human Services

Health Care Financing  
Administration

Ruling No 93-1

Date May 1993

HCFA Rulings are decisions of the Administrator that serve as precedent final opinions and orders and statements of policy and interpretation. They provide clarification and interpretation of complex or ambiguous statutory or regulatory provisions relating to Medicare, Medicaid, Utilization and Quality Control Peer Review, and related matters.

HCFA Rulings are binding on all HCFA components, the Provider Reimbursement Review Board and Administrative Law Judges who hear Medicare appeals. These decisions promote consistency in interpretation of policy and adjudication of disputes.

This Ruling clarifies the position of the Health Care Financing Administration concerning the weight to be given to a treating physician's opinion in determining Medicare Part A coverage of inpatient care in a hospital or skilled nursing facility.



**MEDICARE PROGRAM  
Hospital Insurance Benefits (Part A)**

**WEIGHT TO BE GIVEN TO A TREATING PHYSICIAN'S OPINION IN  
DETERMINING MEDICARE COVERAGE OF INPATIENT CARE IN A  
HOSPITAL OR SKILLED NURSING FACILITY**

**PURPOSE:** This Ruling clarifies the position of the Health Care Financing Administration (HCFA) concerning the weight to be given to a treating physician's opinion in determining coverage of inpatient hospital and skilled nursing facility care. (This Ruling does not by omission or implication endorse the application of the treating physician rule to those types of services that are not discussed in this Ruling.)

**CITATIONS:** Sections 1154, 1156, 1814(a), 1862(a)(1), 1869 and 1879(a) of the Social Security Act (42 U.S.C. 1320c-3, 1320c-5, 1395f(a), 1395y(a)(1), 1395ff and 1395pp(a)); 42 CFR §§405.706(a), 424.10, 424.13, 424.14, 483.20(a) and 483.40.

PERTINENT HISTORY: Two 1991 decisions by the United States Court of Appeals for the Second Circuit remanded cases to the Secretary of the Department of Health and Human Services (the Department) to explain the weight the Department gives to the opinion of the treating physician when making Medicare Part A inpatient hospital coverage determinations. (State of New York o/b/o Holland v. Secretary of Health and Human Services, 927 F.2d 57 (2nd Cir. 1991); State of New York o/b/o Stein v. Secretary of Health and Human Services, 924 F.2d 431 (2nd Cir. 1991)).

Under section 1814(a) of the Social Security Act (the Act), a physician's certification of the need for services is a condition for payment of those services to be made under the Medicare program. In the case of inpatient hospital or skilled nursing facility (SNF) services, the physician's certification of the medical need for the services is only the first step in determining whether those services will be covered. A patient usually is admitted to a hospital only upon the advice of the treating physician. Therefore, for inpatient hospital services to be covered under Part A, one

of the following physician certification provisions must be met:

- For inpatient services of hospitals other than psychiatric hospitals, section 1814(a)(3) of the Act and 42 CFR 424.13 provide that a physician certify that the services the patient receives must be furnished on an inpatient basis for the patient's medical treatment or that inpatient diagnostic study is medically required.
- For inpatient services of psychiatric hospitals, section 1814(a)(2)(A) of the Act and 42 CFR 424.14 provide that a physician certify that the inpatient psychiatric services the patient receives are required for diagnostic study or for treatment that could reasonably be expected to improve the patient's condition.
- For inpatient hospital services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting the teeth, section 1814(a)(2)(D) of the Act provides that a physician certify that because of the individual's underlying medical condition and clinical status or the severity of the dental procedure, hospitalization is

required in connection with the provision of these services.

In addition, 42 CFR 424.13(f) provides that, at the option of a hospital other than a psychiatric hospital, extended stay review by its utilization review committee may take the place of the second and subsequent certifications for cases not subject to the Medicare prospective payment system and for day-outlier cases under the prospective payment system. Under 42 CFR 424.14(e), the same recertification provision applies for psychiatric hospitals.

For SNF services, section 1814(a)(2) of the Act specifies that payment for SNF services may be made only if a physician, or nurse practitioner or clinical nurse specialist working with a physician, certifies that an individual needs daily skilled nursing care or other skilled rehabilitation services, which as a practical matter can only be provided in a SNF on an inpatient basis, for any condition for which the individual was receiving inpatient hospital services before transfer to the SNF.

In the case of SNF services, 42 CFR 483.20(a) provides that an individual will be admitted to a SNF only if the SNF has a physician order for the individual's immediate care at the time of admission. Under 42 CFR 483.40, a physician must sign a recommendation that an individual be admitted to a SNF, and each SNF resident must remain under the care of a physician. A physician must supervise the medical care of each resident, visit each resident at least once every 30 days for the first 90 days after admission, and at least once every 60 days thereafter. At each visit, the physician must review the resident's total program of care, including medications and treatments. The physician must also write, sign, and date progress notes at each visit, and sign and date all orders. Under 42 CFR 483.40(c) and (e), after the initial physician visit, a physician may delegate alternate visits to a physician assistant, nurse practitioner, or clinical nurse specialist.

The general approach to coverage that underlies these certification requirements can be traced back to the Congressional committee reports that accompanied the enactment of the Medicare program in 1965. The Senate Finance Committee emphasized "that the physician is to be

the key figure in determining utilization of health services--and . . . it is a physician who is to decide upon admission to a hospital, order tests, drugs, and treatments, and determine the length of stay." (Report of the Committee on Finance, U.S. Senate, to accompany H.R. 6675, the Social Security Amendments of 1965 (S. Rep. No. 404, Part I, 89th Cong., 1st Sess. 46 (1965))). This reasoning is repeated in regulations at 42 CFR 424.10.

However, meeting the coverage rule requiring the physician's certification does not guarantee that the care provided will be covered. In order to be covered under Medicare Part A, the care must also be "reasonable and necessary". There has always been a statutory prohibition against payment under the Medicare program for services that ". . . are not reasonable and necessary for the diagnosis or treatment of illness or injury . . .". (See section 1862(a)(1) of the Act). Section 1869(a) of the Act makes clear that the final decision concerning entitlement to benefits is the Secretary's alone:

The determination of whether an individual is entitled to benefits under part A or part B, and the determination of the amount of benefits under part A or

part B, and any other determination with respect to a claim for benefits under part A or a claim for benefits with respect to home health services under part B shall be made by the Secretary in accordance with regulations prescribed by him.

See also State of New York o/b/o Bodnar v. Sullivan, 903 F.2d 122, 125 (2d Cir. 1990); see also Goodman v. Sullivan, 891 F.2d 449, 450-51 (2d Cir. 1989).

The Medicare Part A fiscal intermediary or the peer review organization (PRO) acts as a medical review entity for the Secretary. (See section 1154 of the Act for a description of the functions of peer review organizations.)

Historically, these entities have been given very wide discretion in deciding whether or not an inpatient hospital stay or skilled nursing stay was "reasonable and necessary" for the diagnosis or treatment of a particular patient's condition. The medical review entity is charged with acting in accordance with the Medicare law, regulations, national coverage instructions, and accepted standards of medical practice. The decisions of these entities will be the final decisions in such matters unless they are appealed under section 1869 of the Act.

In the vast majority of cases, if the attending physician's certification of the medical need for the services is consistent with other records submitted in support of the claim for payment, the claim is paid. However, if the medical evidence is inconsistent with the physician's certification, the medical review entity considers the attending physician's certification only on a par with the other pertinent medical evidence. The review entity also considers factors such as the condition of the patient upon admission, the nature of the primary diagnosis, the existence of co-morbid conditions, or the actual course of the patient during the confinement (including treatment and progress toward recovery). This function helps insure that each practitioner complies with the basic obligations mandated by section 1156(a) of the Act:

It shall be the obligation of any health care practitioner and any other person (including a hospital or other health care facility, organization, or agency) who provides health care services for which payment may be made (in whole or in part) under this Act, to assure, to the extent of his authority that services or items ordered or provided by such practitioner or person to beneficiaries and recipients under this Act--  
(1) will be provided economically and only when, and to the extent, medically necessary;  
(2) will be of a quality which meets professionally recognized standards of health care; and -

(3) will be supported by evidence of medical necessity and quality in such form and fashion and at such time as may reasonably be required by a reviewing peer review organization in the exercise of its duties and responsibilities.

In determining whether the health care services provided were reasonable and necessary, the medical review entity confines its review to the medical record associated with the inpatient stay, which is a discrete past event. There is no opportunity for a physical examination of the patient by the medical review entity. No judgment of the probable future course of the patient, such as whether the patient could reasonably be expected to participate in substantial gainful activity, is expected. The only questions that can be considered based on the evidence in the medical record are the reasonableness and necessity of the patient's admission to the institution and the necessity of his or her continued stay. Both are discrete past events that can only be reviewed from a documentary medical record. Although the physician must make prospective judgments about the need for initial and continuing inpatient care, the medical review entity has the benefit of hindsight in reviewing a case retrospectively. For this reason, the review criteria set forth in regulations, Rulings, and other pertinent guidelines

recognize that a physician's opinion and medical judgment should be evaluated in terms of the information available to the physician at the time.<sup>1</sup> These criteria recognize that medical judgments may not always be clear cut at any given point in time and permit reasonable leeway in questionable situations, as long as the evaluation is diligent and ongoing. Section 1879(a) of the Act provides for a limitation of liability if neither the provider nor the patient knows, or could reasonably be expected to know, that the care is not covered because it is not reasonable and necessary or constitutes custodial care.

As a result of the relationship that develops between a physician and his or her patient, the physician is in a unique position to incorporate complete medical evidence in

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<sup>1</sup> For example, HCFAR 85-2 contains detailed criteria for use in distinguishing inpatient rehabilitative care in rehabilitation hospitals as opposed to skilled nursing and other levels of care. The information used to evaluate the need for this inpatient rehabilitative care, given in HCFAR 85-2, should be reflected in the patient's medical record.

patient medical records, including his or her opinions and the pertinent medical history of the patient. In effect, a treating physician controls the documentation supporting his or her opinion as to appropriate treatment. In creating the medical assessment, medical history, and discharge notes that become part of the medical record, the physician has ample opportunity to explain in detail why the course of treatment was appropriate in the context of that patient's acute condition and medical history. In addition, the physician has the opportunity to describe and explain aspects of the patient's medical history that may not otherwise be apparent. Thus, the physician is responsible for ensuring that the patient's record includes complete medical information, and this information is the basis for determining the appropriateness of the prescribed treatment. The final determination by the medical review entity should not be based solely on the physician's opinion, but should reflect its evaluation of all documentation contained in the medical record.

We note that the criteria governing how the medical review entity makes its determination do not discount the role of the treating physician. Frequently, the medical review

entity's determination of whether the course of treatment was reasonable and necessary may turn on the comprehensiveness of the evidence furnished by the physician as to the condition of the patient and the medical factors that bear upon his or her treatment.

To summarize, in order to fulfill its obligations to determine whether payment should be made for Part A benefits, the medical review entity "looks behind" the information provided by the treating physician and makes an initial determination based on all the evidence available from the medical record. The information provided by the physician, including the initial certification of inpatient care, the accompanying medical history, medical assessment, discharge notes, and any subsequent certification by a hospital or a skilled nursing facility's utilization review committee, is considered evidence, but not presumptive evidence, that an admission or continued stay is reasonable and necessary. (See 42 CFR 405.706(a).) However, the medical review entity is still responsible for judiciously applying the review criteria published by the Department to the accompanying medical evidence.

RULING: It is HCFA's Ruling that no presumptive weight should be assigned to the treating physician's medical opinion in determining the medical necessity of inpatient hospital or SNF services under section 1862(a)(1) of the Act. A physician's opinion will be evaluated in the context of the evidence in the complete administrative record. Even though a physician's certification is required for payment, coverage decisions are not made based solely on this certification; they are made based on objective medical information about the patient's condition and the services received. This information is available from the claims form and, when necessary, the medical record which includes the physician's certification.

HCFAR 93-14

EFFECTIVE DATE

This Ruling is effective May 18 1993

DATED: MAY 18 1993.

William J. Joby  
Acting Deputy Administrator,  
Health Care Financing  
Administration

# HCFA Rulings

Department of Health  
and Human Services

Health Care Financing  
Administration

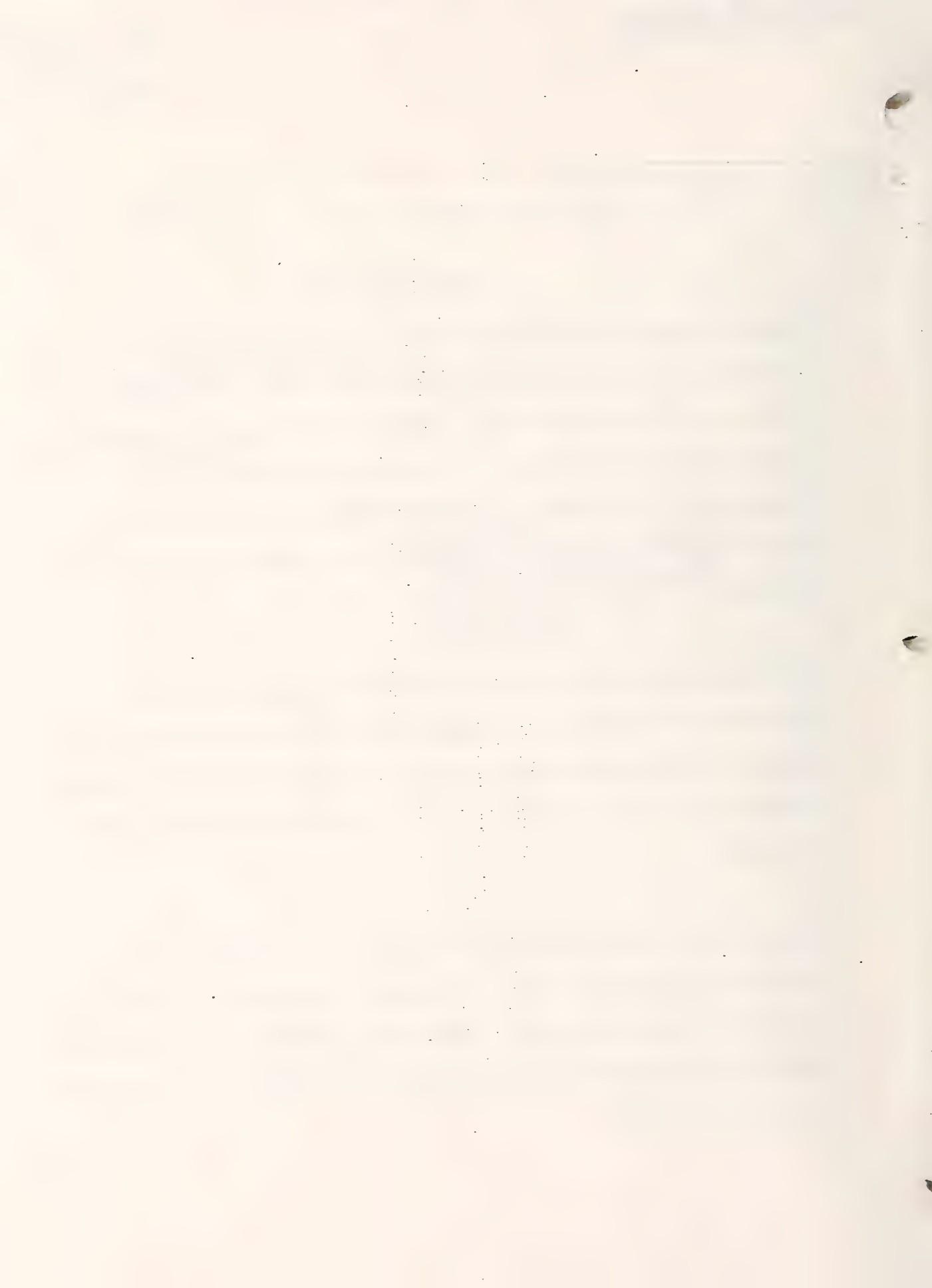
Ruling No 93- 1

Date May 1993

HCFA Rulings are decisions of the Administrator that serve as precedent final opinions and orders and statements of policy and interpretation. They provide clarification and interpretation of complex or ambiguous statutory or regulatory provisions relating to Medicare, Medicaid, Utilization and Quality Control Peer Review, and related matters.

HCFA Rulings are binding on all HCFA components, the Provider Reimbursement Review Board and Administrative Law Judges who hear Medicare appeals. These decisions promote consistency in interpretation of policy and adjudication of disputes.

This Ruling clarifies the position of the Health Care Financing Administration concerning the weight to be given to a treating physician's opinion in determining Medicare Part A coverage of inpatient care in a hospital or skilled nursing facility.



**MEDICARE PROGRAM  
Hospital Insurance Benefits (Part A)**

**WEIGHT TO BE GIVEN TO A TREATING PHYSICIAN'S OPINION IN  
DETERMINING MEDICARE COVERAGE OF INPATIENT CARE IN A  
HOSPITAL OR SKILLED NURSING FACILITY**

**PURPOSE:** This Ruling clarifies the position of the Health Care Financing Administration (HCFA) concerning the weight to be given to a treating physician's opinion in determining coverage of inpatient hospital and skilled nursing facility care. (This Ruling does not by omission or implication endorse the application of the treating physician rule to those types of services that are not discussed in this Ruling.)

**CITATIONS:** Sections 1154, 1156, 1814(a), 1862(a)(1), 1869 and 1879(a) of the Social Security Act (42 U.S.C. 1320c-3, 1320c-5, 1395f(a), 1395y(a)(1), 1395ff and 1395pp(a)); 42 CFR §§405.706(a); 424.10, 424.13, 424.14, 483.20(a) and 483.40.

PERTINENT HISTORY: Two 1991 decisions by the United States Court of Appeals for the Second Circuit remanded cases to the Secretary of the Department of Health and Human Services (the Department) to explain the weight the Department gives to the opinion of the treating physician when making Medicare Part A inpatient hospital coverage determinations. (State of New York o/b/o Holland v. Secretary of Health and Human Services, 927 F.2d 57 (2nd Cir. 1991); State of New York o/b/o Stein v. Secretary of Health and Human Services, 924 F.2d 431 (2nd Cir. 1991)).

Under section 1814(a) of the Social Security Act (the Act), a physician's certification of the need for services is a condition for payment of those services to be made under the Medicare program. In the case of inpatient hospital or skilled nursing facility (SNF) services, the physician's certification of the medical need for the services is only the first step in determining whether those services will be covered. A patient usually is admitted to a hospital only upon the advice of the treating physician. Therefore, for inpatient hospital services to be covered under Part A, one

of the following physician certification provisions must be met:

- For inpatient services of hospitals other than psychiatric hospitals, section 1814(a)(3) of the Act and 42 CFR 424.13 provide that a physician certify that the services the patient receives must be furnished on an inpatient basis for the patient's medical treatment or that inpatient diagnostic study is medically required.
- For inpatient services of psychiatric hospitals, section 1814(a)(2)(A) of the Act and 42 CFR 424.14 provide that a physician certify that the inpatient psychiatric services the patient receives are required for diagnostic study or for treatment that could reasonably be expected to improve the patient's condition.
- For inpatient hospital services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting the teeth, section 1814(a)(2)(D) of the Act provides that a physician certify that because of the individual's underlying medical condition and clinical status or the severity of the dental procedure, hospitalization is

required in connection with the provision of these services.

In addition, 42 CFR 424.13(f) provides that, at the option of a hospital other than a psychiatric hospital, extended stay review by its utilization review committee may take the place of the second and subsequent certifications for cases not subject to the Medicare prospective payment system and for day-outlier cases under the prospective payment system. Under 42 CFR 424.14(e), the same recertification provision applies for psychiatric hospitals.

For SNF services, section 1814(a)(2) of the Act specifies that payment for SNF services may be made only if a physician, or nurse practitioner or clinical nurse specialist working with a physician, certifies that an individual needs daily skilled nursing care or other skilled rehabilitation services, which as a practical matter can only be provided in a SNF on an inpatient basis, for any condition for which the individual was receiving inpatient hospital services before transfer to the SNF.

In the case of SNF services, 42 CFR 483.20(a) provides that an individual will be admitted to a SNF only if the SNF has a physician order for the individual's immediate care at the time of admission. Under 42 CFR 483.40, a physician must sign a recommendation that an individual be admitted to a SNF, and each SNF resident must remain under the care of a physician. A physician must supervise the medical care of each resident, visit each resident at least once every 30 days for the first 90 days after admission, and at least once every 60 days thereafter. At each visit, the physician must review the resident's total program of care, including medications and treatments. The physician must also write, sign, and date progress notes at each visit, and sign and date all orders. Under 42 CFR 483.40(c) and (e), after the initial physician visit, a physician may delegate alternate visits to a physician assistant, nurse practitioner, or clinical nurse specialist.

The general approach to coverage that underlies these certification requirements can be traced back to the Congressional committee reports that accompanied the enactment of the Medicare program in 1965. The Senate Finance Committee emphasized "that the physician is to be

the key figure in determining utilization of health services--and . . . it is a physician who is to decide upon admission to a hospital, order tests, drugs, and treatments, and determine the length of stay." (Report of the Committee on Finance, U.S. Senate, to accompany H.R. 6675, the Social Security Amendments of 1965 (S. Rep. No. 404, Part I, 89th Cong., 1st Sess. 46 (1965)).) This reasoning is repeated in regulations at 42 CFR 424.10.

However, meeting the coverage rule requiring the physician's certification does not guarantee that the care provided will be covered. In order to be covered under Medicare Part A, the care must also be "reasonable and necessary". There has always been a statutory prohibition against payment under the Medicare program for services that ". . . are not reasonable and necessary for the diagnosis or treatment of illness or injury . . .". (See section 1862(a)(1) of the Act). Section 1869(a) of the Act makes clear that the final decision concerning entitlement to benefits is the Secretary's alone:

The determination of whether an individual is entitled to benefits under part A or part B, and the determination of the amount of benefits under part A or

part B, and any other determination with respect to a claim for benefits under part A or a claim for benefits with respect to home health services under part B shall be made by the Secretary in accordance with regulations prescribed by him.

See also State of New York o/b/o Bodnar v. Sullivan, 903 F.2d 122, 125 (2d Cir. 1990); see also Goodman v. Sullivan, 891 F.2d 449, 450-51 (2d Cir. 1989).

The Medicare Part A fiscal intermediary or the peer review organization (PRO) acts as a medical review entity for the Secretary. (See section 1154 of the Act for a description of the functions of peer review organizations.)

Historically, these entities have been given very wide discretion in deciding whether or not an inpatient hospital stay or skilled nursing stay was "reasonable and necessary" for the diagnosis or treatment of a particular patient's condition. The medical review entity is charged with acting in accordance with the Medicare law, regulations, national coverage instructions, and accepted standards of medical practice. The decisions of these entities will be the final decisions in such matters unless they are appealed under section 1869 of the Act.

In the vast majority of cases, if the attending physician's certification of the medical need for the services is consistent with other records submitted in support of the claim for payment, the claim is paid. However, if the medical evidence is inconsistent with the physician's certification, the medical review entity considers the attending physician's certification only on a par with the other pertinent medical evidence. The review entity also considers factors such as the condition of the patient upon admission, the nature of the primary diagnosis, the existence of co-morbid conditions, or the actual course of the patient during the confinement (including treatment and progress toward recovery). This function helps insure that each practitioner complies with the basic obligations mandated by section 1156(a) of the Act:

It shall be the obligation of any health care practitioner and any other person (including a hospital or other health care facility, organization, or agency) who provides health care services for which payment may be made (in whole or in part) under this Act, to assure, to the extent of his authority that services or items ordered or provided by such practitioner or person to beneficiaries and recipients under this Act--  
(1) will be provided economically and only when, and to the extent, medically necessary;  
(2) will be of a quality which meets professionally recognized standards of health care; and

(3) will be supported by evidence of medical necessity and quality in such form and fashion and at such time as may reasonably be required by a reviewing peer review organization in the exercise of its duties and responsibilities.

In determining whether the health care services provided were reasonable and necessary, the medical review entity confines its review to the medical record associated with the inpatient stay, which is a discrete past event. There is no opportunity for a physical examination of the patient by the medical review entity. No judgment of the probable future course of the patient, such as whether the patient could reasonably be expected to participate in substantial gainful activity, is expected. The only questions that can be considered based on the evidence in the medical record are the reasonableness and necessity of the patient's admission to the institution and the necessity of his or her continued stay. Both are discrete past events that can only be reviewed from a documentary medical record. Although the physician must make prospective judgments about the need for initial and continuing inpatient care, the medical review entity has the benefit of hindsight in reviewing a case retrospectively. For this reason, the review criteria set forth in regulations, Rulings, and other pertinent guidelines

recognize that a physician's opinion and medical judgment should be evaluated in terms of the information available to the physician at the time.<sup>1</sup> These criteria recognize that medical judgments may not always be clear cut at any given point in time and permit reasonable leeway in questionable situations, as long as the evaluation is diligent and ongoing. Section 1879(a) of the Act provides for a limitation of liability if neither the provider nor the patient knows, or could reasonably be expected to know, that the care is not covered because it is not reasonable and necessary or constitutes custodial care.

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entity's determination of whether the course of treatment was reasonable and necessary may turn on the comprehensiveness of the evidence furnished by the physician as to the condition of the patient and the medical factors that bear upon his or her treatment.

To summarize, in order to fulfill its obligations to determine whether payment should be made for Part A benefits, the medical review entity "looks behind" the information provided by the treating physician and makes an initial determination based on all the evidence available from the medical record. The information provided by the physician, including the initial certification of inpatient care, the accompanying medical history, medical assessment, discharge notes, and any subsequent certification by a hospital or a skilled nursing facility's utilization review committee, is considered evidence, but not presumptive evidence, that an admission or continued stay is reasonable and necessary. (See 42 CFR 405.706(a).) However, the medical review entity is still responsible for judiciously applying the review criteria published by the Department to the accompanying medical evidence.

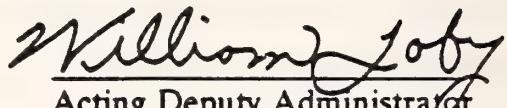
RULING: It is HCFA's Ruling that no presumptive weight should be assigned to the treating physician's medical opinion in determining the medical necessity of inpatient hospital or SNF services under section 1862(a)(1) of the Act. A physician's opinion will be evaluated in the context of the evidence in the complete administrative record. Even though a physician's certification is required for payment, coverage decisions are not made based solely on this certification; they are made based on objective medical information about the patient's condition and the services received. This information is available from the claims form and, when necessary, the medical record which includes the physician's certification.

HCFAR 93-14

EFFECTIVE DATE

This Ruling is effective May 18 1993

DATED: MAY 18 1993.

  
Acting Deputy Administrator,  
Health Care Financing  
Administration

**How to use these separators**

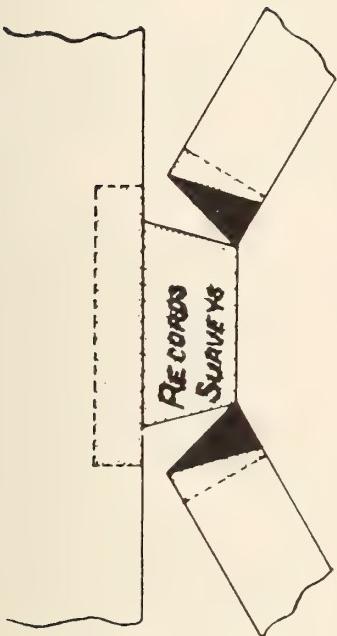
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# HCFA Rulings

Department of Health  
and Human Services

Health Care Financing  
Administration

Ruling No HCFAR-92-1

Date August 1992

**HCFA Rulings** are decisions of the Administrator that serve as precedent final opinions and orders and statements of policy and interpretation. They provide clarification and interpretation of complex or ambiguous statutory or regulatory provisions relating to Medicare, Medicaid, Utilization and Quality Control Peer Review, and related matters.

**HCFA Rulings** are binding on all HCFA components, the Provider Reimbursement Review Board and Administrative Law Judges who hear Medicare appeals. These decisions promote consistency in interpretation of policy and adjudication of disputes.

This Ruling announces the Health Care Financing Administration's determination that current regulations based on time limited agreements for providers of nursing services, under the Medicare and Medicaid programs, are inconsistent with the survey, certification, and enforcement provisions of sections 1819 and 1919 of the Social Security Act. Accordingly, those provisions of program regulations that are based on such time limited agreements are determined to be superseded by and inconsistent with sections 1819 and 1919 of the Act and will no longer be followed.



**MEDICARE AND MEDICAID PROGRAMS**

**Hospital Insurance Benefits (Part A) and Medical Assistance Programs**

**Skilled Nursing Facility and Nursing Facility Provider Agreements**

**PURPOSE:** This ruling provides notice of the Health Care Financing Administration's (HCFA) determination that time limited agreements for providers of nursing services under the Medicare and Medicaid programs are inconsistent with the implementation of the nursing home reform provisions of sections 1819 and 1919 of the Social Security Act (the Act). Accordingly, those provisions of program regulations that are based on such time limited agreements are determined to be superseded by and inconsistent with sections 1819 and 1919 of the Act and will no longer be followed.

**CITATIONS:** Sections 1819 and 1919 of the Social Security Act (42 U.S.C. 1395i-3 and 1396r); 42 CFR §§442.15, 442.16, 442.109, 442.110, 488.50, 489.15 and 489.16.

**PERTINENT HISTORY:** As part of the Social Security Amendments of 1972 (Pub. L. 92-603), the Congress amended section 1866 of the Act to require that Medicare provider agreements with skilled

nursing facilities (SNFs) not exceed 12 months in duration. Although the Congress removed this requirement in its enactment of section 2153 of the Omnibus Budget Reconciliation Act of 1981 (Pub. L. 97-35), HCFA regulations retained the provisions governing time limited agreements and they have remained in force to the present.

In December 1987, the Congress enacted the nursing home reform provisions of the Omnibus Budget Reconciliation Act of 1987 (Pub. L. 100-203), which significantly rewrote the rules that govern the survey, certification, and enforcement responsibilities of the Secretary and the States for both the Medicare and Medicaid programs. These provisions in large measure reflected the conclusions reached by the National Academy of Science's Institute of Medicine (IOM) in its 1986 review of nursing home regulations. The survey, certification, and enforcement measures of this legislation reconfigured the way in which HCFA and the States would track nursing home compliance with Federal requirements and approach enforcement strategies. While we believed at first that we could continue to implement the regulations' time limited agreement requirements until they could be replaced by new survey, certification, and enforcement regulations, we now believe that the continued implementation of these provisions frustrates many aspects of nursing home reform and, in a practical way, has rendered them inoperable.

Sections 1819(g)(2) and 1919(g)(2) of the Act require the Secretary and States to implement a flexible survey cycle for Medicare SNFs and Medicaid nursing facilities so that surveys are conducted at intervals not later than 15 months after the date of the previous survey with an annual State-wide average of 12 months. The legislative history and the IOM study are plain in their stated reasons for this change from the rigid system of having surveys for all facilities follow a 12-month cycle. First, a flexible survey cycle provides less predictability to the scheduling of surveys, thus reducing the opportunities for certain providers, by anticipating the survey, to achieve only temporary compliance for the short term period around the time of survey. To further establish the necessity for unpredictability, these sections of the statute expressly provide for civil money penalties for those persons who notify a facility of the time or date of standard surveys. Second, flexible survey cycles allow survey agencies to better allocate their limited resources by increasing the frequency of surveys for problem facilities while allowing other facilities with a better record of compliance to be less rigorously monitored. Additionally, because time limited agreements have automatic cancellation clauses, a significant paperwork and recordkeeping burden results from the frequent need to conduct resurveys as a means of avoiding provider agreement expirations.

The 12-month provider agreement limitation and the other HCFA regulations that contemplate fixed expiration dates for such agreements do not allow for the full implementation of these stated legislative goals. The scheduling of surveys is almost entirely predictable; there is no discrimination between problem and non-problem facilities that would allow for the better allocation of survey resources; and there is the continued paperwork and recordkeeping burden of time limited agreements. Even the House Budget Committee expressed its view that the continuation of fixed 12-month provider agreements would "conflict" with the new provisions of the statute. (H.R. Budget Comm. Rep. No. 391, 100th Cong., 1st Sess. 467 (1987).)

Further, the enforcement provisions of nursing home reform, set forth at sections 1819(h) and 1919(h) of the Act, are designed to work in the context of provider agreements that do not have a fixed ending date. Specifically, sections 1819(h)(2)(C) and 1919(h)(3)(D) of the Act speak to the ability of the Secretary to continue payments for up to 6 months after the identification of deficiencies if certain criteria, described in those sections, are met. Sections 1819(h)(2)(D) and 1919(h)(2)(C) of the Act require the Secretary and States to impose a ban on the payment for new admissions should deficient facilities fail to achieve full compliance within 3 months after they have been determined

not to comply with Federal requirements. In both cases, these remedies make sense only where a facility's provider agreement has no set expiration date.

We reach this conclusion because under the current survey system where surveys are typically conducted shortly before the expiration of provider agreements, facilities would have only the shortest period of time to correct deficiencies if they are to be entitled to renewed agreements. The statutory remedies described above, however, contemplate periods of time that far exceed what would be available under the current system for providers to achieve compliance. For HCFA and the States to attempt to fit the current survey system into the procedures described in sections 1819(h) and 1919(h) of the Act would require the wholesale revamping of surveys so that they occur no later than mid-way through the term of the 12-month provider agreement. Such a radical departure from more than twenty years of practice would require the kind of massive reallocation of survey resources that is not possible under the current system and would likely cause many facilities to go unsurveyed by the time their time limited agreements are scheduled to expire. Of equal significance, we do not believe that the Congress would approve of a survey system in which decisions about the renewal of a provider agreement are made as far as 6 months prior to the expiration of that agreement, since there is very little

likelihood that determinations of compliance made so far in advance would have any relevance to the degree of facility compliance at the time the agreement is set to expire. None of these difficulties would present themselves if, as the Congress intended, there were no time limited provider agreements.

The resulting poor fit between current practice under time limited agreements and the enforcement provisions of sections 1819 and 1919 of the Act has forced HCFA and the States to rely almost exclusively on the termination of provider agreements in order to have a dispositive solution to provider non-compliance at the time the agreements expire. This is precisely a consequence the Congress wished to avoid. (H.R. Budget Comm. Rep. No. 391, 100th Cong., 1st Sess. 471 (1987).) The broad array of alternative sanctions that the Congress has given the Secretary and the States is rendered meaningless by the imperative to assure that some final action is taken with respect to each provider every 12 months. To this extent, we believe that the current regulations governing time limited agreements prevent HCFA and the States from implementing nursing home reform in the manner intended by the Congress.

**RULING:** Current regulations for the Medicare and Medicaid programs that govern time limited agreements are inconsistent with the survey, certification, and enforcement provisions of

sections 1819 and 1919 of the Act. Accordingly, we consider these sections of the statute to have superseded all those regulations (specified above) that speak to time limited agreements for both programs.

EFFECTIVE DATE

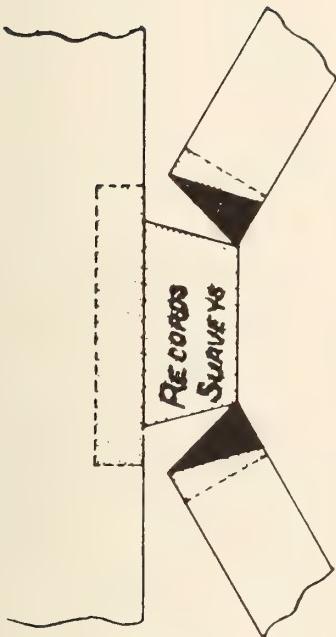
This Ruling is effective August 26, 1992.

AUG 26 1992  
DATED: \_\_\_\_\_

William Toby, Jr.  
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Acting Deputy Administrator,  
Health Care Financing  
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## MEDICARE PROGRAM

Hospital Insurance and Supplementary Medical Insurance Benefits  
(Parts A and B)

Notice of Decision to Follow a Consent Order Providing for the Discontinued Application of the 1986 Medicare Malpractice Rule and a Reversion to the Pre-1979 Utilization Method of Paying Certain Hospital Malpractice Insurance Costs

PURPOSE: This Ruling provides notice of the determination of the Health Care Financing Administration (HCFA) that it will follow the Consent Order in Children's National Medical Center, et al. v. Sullivan, Civil Action No. 90-1362-WBB (D.D.C. July 16, 1991) (Children's National), which provides that the 1986 Medicare malpractice rule, 42 CFR 413.56, is invalid and shall not be enforced. As explained below, the Children's National Consent Order reflects HCFA's determination that it cannot continue to apply or defend the 1986 rule due to the fact that the agency has not completed the implementation of that regulation. The Ruling also explains how HCFA and its fiscal intermediaries will pay certain hospital malpractice insurance cost claims and appeals that are now pending before the intermediaries, the Provider Reimbursement Review Board (PRRB), the Deputy Administrator of HCFA, and in the Federal courts in accordance with the pre-1979 utilization method.

CITATIONS: Sections 1861(v)(1)(A), 1871, and 1886(d)(1)(B) of the Social Security Act (42 U.S.C. 1395x(v)(1)(A), 1395hh, and 1395ww(d)(1)(B)); 42 CFR 412.20-412.32, 413.53(a)(1)(i), and 413.56; 51 FR 11142 (April 1, 1986) and 52 FR 9833 (March 27, 1987).

PERTINENT HISTORY: For covered services furnished to Medicare beneficiaries in cost reporting periods beginning before October 1, 1983, hospitals and other providers are entitled to payment of the lesser of the reasonable cost or the customary charges for these services. 42 U.S.C. 1395f(b)(1). The statutory definition of "reasonable cost," 42 U.S.C. 1395x(v)(1)(A), authorizes the Secretary to promulgate "regulations establishing the method or methods to be used, and the items to be included, in determining such costs." Pursuant to statutory authority, the Secretary has adopted numerous cost determination regulations, see 42 CFR Part 413, including cost apportionment regulations, see 42 CFR 413.50 through 413.56, such as the 1986 malpractice rule.

For inpatient hospital services furnished in cost reporting periods beginning on or after October 1, 1983, general acute-care, short-stay hospitals are paid under the Medicare prospective payment system on the basis of predetermined fixed payment rates for each discharge, according to a patient's

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HCFA Rulings are binding on all HCFA components, the Provider Reimbursement Review Board and Administrative Law Judges who hear Medicare appeals. These decisions promote consistency in interpretation of policy and adjudication of disputes.

This Ruling announces the Health Care Financing Administration's determination to follow the Consent Order approved by the United States District Court for the District of Columbia with respect to certain claims or appeals that have been filed or could be filed challenging the validity of the 1986 Medicare malpractice rule. As a result, HCFA will discontinue application of the 1986 rule and revert to the pre-1979 utilization method of paying certain hospital malpractice insurance costs.



"diagnosis-related group" (DRG). See 42 U.S.C. 1395ww(d); 42 CFR Part 412. However, hospital outpatient services are still paid under the cost-based reimbursement system, as are inpatient services furnished by certain specialty hospitals and distinct-part hospital units that are excluded from the prospective payment system. (42 U.S.C. 1395ww(d)(1)(B); 42 CFR 412.20 through 412.32.)

**Malpractice Insurance Costs** -- For cost reporting periods beginning prior to July 1, 1979, provider malpractice insurance costs (that is, the cost of a malpractice insurance policy or of contributions made to a self-insurance fund) were reimbursed in accordance with the pre-1979 utilization method, which required, first, that malpractice insurance costs be included in the general and administrative cost center (G&A pool) along with other provider overhead costs and, second, that insurance costs be apportioned to the Medicare program in accordance with the provider's Medicare patient utilization rate. See 51 FR 11142-43 (April 1, 1986). See also 42 CFR 405.452(b)(1), redesignated as 42 CFR 413.53(a)(1)(i). In 1979, the Secretary determined that it was necessary and appropriate to remove malpractice insurance costs from the G&A pool and pay those costs in accordance with the 1979 malpractice rule, which, for cost reporting periods beginning on or after July 1, 1979, directly apportioned a provider's insurance costs based on the ratio of malpractice losses paid to Medicare patients compared to losses

paid to all patients. See 51 FR 11143. See also 44 FR 31641 (June 1, 1979), adding 42 CFR 405.452(b)(1)(ii), redesignated as 42 CFR 405.452(a)(1)(ii).

In response to litigation challenging the 1979 malpractice rule, see Tallahassee Memorial Regional Medical Center v. Bowen, 815 F.2d 1435, 1441 n.7 (11th Cir. 1987), cert. denied, 485 U.S. 1020 (1988) (collecting cases), and the availability of new data, the Secretary promulgated an interim final rule with comment period, which, effective May 1, 1986, replaced the 1979 malpractice rule with a new methodology for apportioning hospital malpractice insurance costs in "the 1986 malpractice rule." See 51 FR 11142, 11195-96, adding 42 CFR 405.457 (April 1, 1986), redesignated as 42 CFR 413.56. The 1986 regulation is based on a hospital's Medicare utilization rate, in addition to including aspects of the claims-paid approach of the 1979 rule. See 42 CFR 413.56(b).

Subsequently, the Secretary confirmed the finality of the 1986 malpractice rule and responded to public comments on the interim final rule. 52 FR 9833 (March 27, 1987). However, as a result of consideration of two comments and reevaluation of pertinent data, the Secretary revised one implementing policy for the 1986 rule by establishing separate sets of "scaling factor formula" values for general acute-care, short-stay hospitals subject to the prospective payment system and for specialty hospitals

excluded from the prospective payment system. See 52 FR 9836. The scaling factor formula values originally established in the preamble to the 1986 interim final rule, see 51 FR at 11145-48, 11195-96, applied to all hospitals and were based on data for both general acute-care, short-stay hospitals (subject to the prospective payment system) and specialty hospitals excluded from the prospective payment system. The 1987 confirmation document established new formula values for general acute-care, short-stay hospitals that are based solely on data for such hospitals and which happen to be identical to the values established in the 1986 interim final rule. See 52 FR at 9836. The 1987 confirmation document further provided that separate formula values were to be established for specialty hospitals excluded from the prospective payment system, but in the interim the values established originally in the 1986 interim final rule would continue to govern specialty hospitals. See 52 FR 9836. As explained below, however, HCFA has not developed all the scaling factor formula values that are required for full implementation of the 1986 rule.

Due to the issuance of Health Care Financing Administration Ruling 89-1 (January 26, 1989) (HCFA Ruling 89-1) and the advent of the prospective payment system, the 1986 malpractice rule now has a limited scope of applicability. As promulgated initially, the 1986 malpractice rule applied retroactively, subject to the Medicare program's general rules of administrative finality, to

cost reporting periods beginning on or after July 1, 1979. See 42 CFR 413.56(a). However, HCFA discontinued retroactive application of the 1986 malpractice rule in HCFA Ruling 89-1, which was issued in response to Bowen v. Georgetown University Hospital, 488 U.S. 204 (1988) (Georgetown I), wherein the Supreme Court invalidated retroactive application of the 1984 Medicare wage index rule. HCFA Ruling 89-1 interprets the Georgetown I decision to control properly pending, and not otherwise settled, malpractice insurance cost reimbursement claims for cost reporting periods beginning before May 1, 1986, the effective date of the 1986 malpractice rule, and that Ruling further requires that these claims be paid under the pre-1979 utilization method.

While HCFA Ruling 89-1 largely limited the application of the 1986 malpractice rule to cost reporting periods beginning on or after May 1, 1986, the advent of the prospective payment system further circumscribed the role of the 1986 rule in hospital reimbursement. For hospitals subject to the prospective payment system, malpractice insurance costs attributable to inpatient services are subsumed under the prospectively determined payment rates that are applied to the various DRGs. Thus, the 1986 malpractice rule only governs malpractice insurance costs attributable to outpatient services for hospitals subject to the prospective payment system, and all services furnished by specialty hospitals and distinct-part hospital units excluded

from the prospective payment system for cost reporting periods beginning on or after May 1, 1986.

The Children's National Consent Order -- The Consent Order in the Children's National case resulted from HCFA's efforts to develop, consistent with the 1987 confirmation document, see 52 FR 9836, separate scaling factor formula values for hospitals excluded from the prospective payment system. In the course of investigating this matter, HCFA determined that it is also necessary to develop separate formula values for malpractice insurance costs attributable to hospital outpatient services and for costs attributable to inpatient services furnished by facilities excluded from the prospective payment system. However, HCFA has not derived separate formula values for inpatient and outpatient services for "the R factor" in the formula (that is, the national Medicare malpractice loss ratio, as adjusted for associated claims adjustment expense), due to the difficulty of securing hospital data attributing malpractice claims (and associated claims adjustment expense) separately to outpatient services and inpatient services. Moreover, separate scaling factor formula values for hospitals excluded from the prospective payment system have not been developed.

The plaintiff-hospitals in the Children's National case challenged the agency's use of the 1986 malpractice rule to determine, for their FY 1987 or FY 1988 cost reporting periods,

their payment for malpractice insurance costs attributable to outpatient services and, in the case of hospital facilities excluded from the prospective payment system, inpatient services. These plaintiffs alleged that the 1986 malpractice rule is invalid because the scaling factor formula values were derived exclusively from inpatient data for general acute-care, short-stay hospitals (subject to the prospective payment system) whereas the 1986 rule applies, due to HCFA Ruling 89-1 and the advent of the prospective payment system, only to outpatient services and inpatient services furnished by hospitals (or units thereof) excluded from the prospective payment system. In light of the fact that HCFA has not developed the additional scaling factor formula values necessary to complete implementation of the 1986 rule, the agency entered into the Consent Order which provides that the 1986 malpractice rule is invalid and shall not be enforced. The Consent Order was approved by the United States District Court for the District of Columbia on July 16, 1991.

Since separate scaling factor formula values for outpatient services and for inpatient services furnished by hospital facilities excluded from the prospective payment system have not been developed, the agency has determined to follow the Consent Order by ceasing application of the 1986 malpractice rule and instead reverting to the pre-1979 utilization method. Specifically, HCFA is instructing the intermediaries to pay properly pending claims or appeals for hospital malpractice

insurance costs attributable to outpatient services, or, in the case of hospitals (or units thereof) excluded from the prospective payment system for inpatient services, for cost reporting periods beginning on or after May 1, 1986, in accordance with the pre-1979 utilization method.

For a claim with respect to a cost reporting period to be "properly pending" all of the following requirements must be met:

(1) The hospital must have timely filed its cost report with its intermediary. (2) The cost report must state the amount of malpractice insurance costs incurred for that year. (Hospitals that filed their cost reports in conformance with the 1986 rule, thereby "self-disallowing" the incremental cost that otherwise would have been payable under the utilization methodology, will be treated as having claimed payment under the pre-1979 utilization methodology.) (3) A notice of program reimbursement has not been issued pertaining to the claim.

For an appeal with respect to a cost reporting period to be "properly pending", all of the following requirements must be met:

(1) An initial notice of program reimbursement (NPR) must have been issued reflecting application of the 1986 malpractice rule. (2) The hospital must have timely filed an appeal of the intermediary's disallowance which must currently be pending before the intermediary, the PRRB, the HCFA Administrator, or the

courts. Hospitals which are within the time period for filing such an appeal also meet this requirement. (Hospitals that self-disallowed payment under the pre-1979 utilization methodology must have appealed the initial notice of program reimbursement.)

See 42 U.S.C. 1395oo; 42 C.F.R. Part 405, Subpart R.

HCFA's nationwide acquiescence in the Children's National Consent Order renders moot for lack of an actual case or controversy all properly pending appeals challenging the 1986 malpractice rule for cost reporting periods beginning on or after May 1, 1986, provided that such appeals satisfy the jurisdictional requirements of 42 U.S.C. 1395oo or 42 CFR 405.1811 and are otherwise subject to the terms of this Ruling. HCFA is taking the steps necessary to ensure prompt payment of claims under this Ruling in each properly pending Federal court case seeking hospital malpractice insurance cost reimbursement under the pre-1979 utilization method.

In order to resolve in an orderly manner properly pending administrative appeals that have been rendered moot by the agency's nationwide acquiescence in the Children's National Consent Order and to facilitate payment of affected reimbursement claims (described above), the administrative tribunal (that is, the intermediary, the PRRB, or the Deputy Administrator of HCFA) before which such appeal is pending will, first, determine whether the appeal satisfies the jurisdictional prerequisites

imposed by 42 U.S.C. 1395oo or 42 CFR 405.1811; and, second, if the applicable jurisdictional requirements are satisfied, then will make a determination as to whether the hospital is entitled to payment of its reimbursement claims under the terms of this Ruling. In the event such a favorable determination is made in an appeal pending before the PRRB or the Deputy Administrator of HCFA, the appeal will be remanded to the appropriate intermediary for payment under the terms of this Ruling.

RULING: It is HCFA's Ruling that the Consent Order in Children's National, supra, controls and thereby renders moot for lack of an actual case or controversy properly pending appeals challenging the 1986 Medicare malpractice rule, 42 CFR 413.56, for cost reporting periods beginning on or after May 1, 1986, provided that such appeals satisfy the jurisdictional requirements of 42 U.S.C. 1395oo or 42 CFR 405.1811. Accordingly, HCFA is instructing the intermediaries to pay under the pre-1979 utilization method any properly pending claim or appeal for hospital malpractice insurance costs attributable to outpatient services or, in the case of hospitals (or units thereof) excluded from the prospective payment system, for inpatient services, for cost reporting periods beginning on or after May 1 1986.

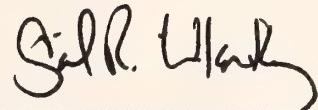
It is also HCFA's Ruling that in order to ensure that the foregoing Ruling will be implemented in an expeditious and orderly manner with respect to properly pending appeals of the

above-described malpractice insurance cost reimbursement issues, HCFA will take appropriate measures in the Federal courts to ensure prompt payment of claims in properly pending appeals under the pre-1979 utilization method. Similarly, it is HCFA's Ruling that, for any claim or appeal of the above-described malpractice insurance cost reimbursement issues that are pending administratively (that is, before the Deputy Administrator of HCFA, the PRRB, or the intermediary), that the administrative tribunal will, first, determine whether the appeal satisfies the pertinent jurisdictional prerequisites, 42 U.S.C. 1395oo or 42 CFR 405.1811; and, second, if the applicable jurisdictional requirements are satisfied, then a determination will be made as to whether the hospital is entitled to payment of its reimbursement claims under the terms of this Ruling. In the event such a favorable determination is made in an appeal pending before the PRRB or the Deputy Administrator of HCFA, the case will be remanded to the appropriate intermediary for payment under the terms of this Ruling.

EFFECTIVE DATE

This Ruling is effective September 30, 1991.

DATED: 9/29/91



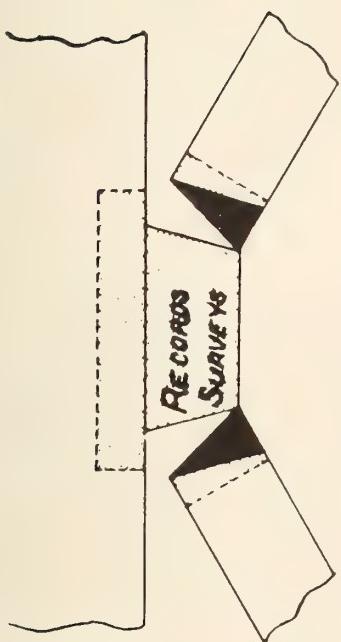
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Gail R. Wilensky, Ph.D.  
Administrator, Health Care  
Financing Administration



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# HCFA Rulings

Department of Health  
and Human Services

Health Care Financing  
Administration

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Ruling No. HCFAR-90-1

Date June 1990

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HCFA RULINGS are decisions of the Administrator that serve as precedent final opinions and orders and statements of policy and interpretation. They provide clarification and interpretation of complex or ambiguous statutory or regulatory provisions relating to Medicare, Medicaid, Utilization and Quality Control Peer Review, and related matters.

HCFA RULINGS are binding on all HCFA components, the Provider Reimbursement Review Board and Administrative Law Judges who hear Medicare appeals. These decisions promote consistency in interpretation of policy and adjudication of disputes.

THIS RULING restates HCFA's policy regarding Medicare coverage of seat lifts as generally provided in 42 CFR 405.514 for durable medical equipment (DME) and as specifically provided in section 60-8 of the Medicare Coverage Issues Manual (54 FR 34555 (August 21, 1989)) for seat lifts.



MEDICARE PROGRAM

Supplementary Medical Insurance Benefits (Part B)

CRITERIA FOR MEDICARE COVERAGE OF SEAT LIFTS

HCFAR-90-1

PURPOSE: This ruling restates Health Care Financing Administration (HCFA) policy regarding Medicare coverage of seat lifts.

CITATIONS: Sections 1832(a), 1861(n) and (s)(6), and 1862(a)(1) of the Social Security Act (the Act) (42 U.S.C. 1395k, 1395x(n) and (s)(6), and 1395y(a)(1)); 42 CFR 405.514; 60-8 of the Medicare Coverage Issues Manual (54 FR 34555 (August 21, 1989)).

PERTINENT HISTORY: Medicare coverage of durable medical equipment (DME) is based on sections 1832(a), 1861(n) and (s)(6), and 1862(a)(1) of the Social Security Act.

RULING: Section 60-8 of the Medicare Coverage Issues Manual establishes our national coverage policy for seat lifts. The existing Manual provisions state the following:

Reimbursement may be made for the rental or purchase of a medically necessary seat lift when prescribed by a physician for a patient with severe arthritis of the hip or knee and patients with muscular dystrophy or other neuromuscular diseases when it has been determined the



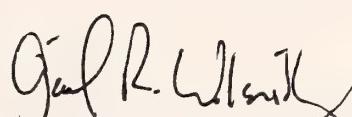
patient can benefit therapeutically from use of the device. In establishing medical necessity for the seat lift, the evidence must show that the item is included in the physician's course of treatment, that it is likely to effect improvement, or arrest or retard deterioration in the patient's condition, and the severity of the condition is such that the alternative would be bed or chair confinement.

Coverage of seat lifts is limited to those types which operate smoothly, can be controlled by the patient, and effectively assist a patient in standing up and sitting down without other assistance. Excluded from coverage is the type of lift which operates by a spring release mechanism with a sudden, catapult-like motion and jolts the patient from a seated to a standing position. [Carriers must] limit the payment for units which incorporate a recliner feature along with the seat lift to the amount payable for a seat lift without this feature.

These longstanding criteria are to be applied in all decisions affecting Medicare coverage of seat lifts and all types of combination lift-chairs.

EFFECTIVE DATE: This Ruling is effective June 11, 1990.

DATE: June 11, 1990

  
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Gail R. Wilensky, Ph.D.  
Administrator, Health Care  
Financing Administration



# HCFA Rulings

Department of Health  
and Human Services

Health Care Financing  
Administration

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Ruling No. HCFAR-90-1

Date June 1990

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THIS RULING restates HCFA's policy regarding Medicare coverage of seat lifts as generally provided in 42 CFR 405.514 for durable medical equipment (DME) and as specifically provided in section 60-8 of the Medicare Coverage Issues Manual (54 FR 34555 (August 21, 1989)) for seat lifts.



## MEDICARE PROGRAM

## Supplementary Medical Insurance Benefits (Part B)

## CRITERIA FOR MEDICARE COVERAGE OF SEAT LIFTS

HCFAR-90-1

PURPOSE: This ruling restates Health Care Financing Administration (HCFA) policy regarding Medicare coverage of seat lifts.

CITATIONS: Sections 1832(a), 1861(n) and (s)(6), and 1862(a)(1) of the Social Security Act (the Act) (42 U.S.C. 1395k, 1395x(n) and (s)(6), and 1395y(a)(1)); 42 CFR 405.514; 60-8 of the Medicare Coverage Issues Manual (54 FR 34555 (August 21, 1989)).

PERTINENT HISTORY: Medicare coverage of durable medical equipment (DME) is based on sections 1832(a), 1861(n) and (s)(6), and 1862(a)(1) of the Social Security Act.

RULING: Section 60-8 of the Medicare Coverage Issues Manual establishes our national coverage policy for seat lifts. The existing Manual provisions state the following:

Reimbursement may be made for the rental or purchase of a medically necessary seat lift when prescribed by a physician for a patient with severe arthritis of the hip or knee and patients with muscular dystrophy or other neuromuscular diseases when it has been determined the



patient can benefit therapeutically from use of the device. In establishing medical necessity for the seat lift, the evidence must show that the item is included in the physician's course of treatment, that it is likely to effect improvement, or arrest or retard deterioration in the patient's condition, and the severity of the condition is such that the alternative would be bed or chair confinement.

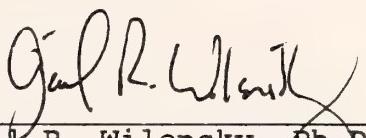
Coverage of seat lifts is limited to those types which operate smoothly, can be controlled by the patient, and effectively assist a patient in standing up and sitting down without other assistance. Excluded from coverage is the type of lift which operates by a spring release mechanism with a sudden, catapult-like motion and jolts the patient from a seated to a standing position. [Carriers must] limit the payment for units which incorporate a recliner feature along with the seat lift to the amount payable for a seat lift without this feature.

These longstanding criteria are to be applied in all decisions affecting Medicare coverage of seat lifts and all types of combination lift-chairs.

EFFECTIVE DATE: This Ruling is effective June 11, 1990.

DATE:

June 11, 1990

  
Gail R. Wilensky  
Administrator, Health Care  
Financing Administration

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# HCFA Rulings

Department of Health

and Human Services

Health Care Financing

Administration

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Ruling No. HCFAR-90-1

Date June 1990

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MEDICARE PROGRAM

Supplementary Medical Insurance Benefits (Part B)

CRITERIA FOR MEDICARE COVERAGE OF SEAT LIFTS

HCFAR-90-1

PURPOSE: This ruling restates Health Care Financing Administration (HCFA) policy regarding Medicare coverage of seat lifts.

CITATIONS: Sections 1832(a), 1861(n) and (s)(6), and 1862(a)(1) of the Social Security Act (the Act) (42 U.S.C. 1395k, 1395x(n) and (s)(6), and 1395y(a)(1)); 42 CFR 405.514; 60-8 of the Medicare Coverage Issues Manual (54 FR 34555 (August 21, 1989)).

PERTINENT HISTORY: Medicare coverage of durable medical equipment (DME) is based on sections 1832(a), 1861(n) and (s)(6), and 1862(a)(1) of the Social Security Act.

RULING: Section 60-8 of the Medicare Coverage Issues Manual establishes our national coverage policy for seat lifts. The existing Manual provisions state the following:

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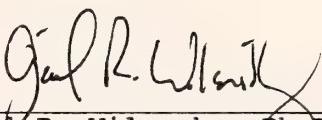
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EFFECTIVE DATE: This Ruling is effective June 11, 1990.

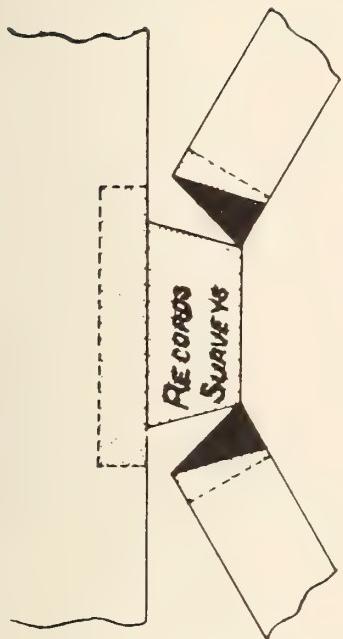
DATE: June 11, 1990

  
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Gail R. Wilensky, Ph.D.  
Administrator, Health Care  
Financing Administration



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# **HCFA Rulings**

**Department of Health  
and Human Services**

**Health Care Financing  
Administration**

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Ruling No. **HCFAR-89-2**

Date **OCTOBER 1989**

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**HCFA Rulings** are binding on all HCFA components, the Provider Reimbursement Review Board and Administrative Law Judges who hear Medicare appeals. These decisions promote consistency in interpretation of policy and adjudication of disputes.

This Ruling establishes that HCFA's application of the absolute limit provided in 42 CFR 417.532(a)(3) on reasonable cost reimbursement to health maintenance organizations and competitive medical plans is inconsistent with recent court of appeals decisions, which have addressed absolute cost limits in other Medicare contexts.



**MEDICARE PROGRAM**

**Health Maintenance Organizations and Competitive Medical Plans**

**Notice of Intent to Settle HMO and CMP Cost Reports for Periods Beginning on or after January 1, 1986, Without Application of Absolute Cost Limits.**

HCFAR 89-2

**PURPOSE:** This Ruling provides notice of the Health Care Financing Administration's (HCFA's) determination that application of the absolute limit provided in 42 C.F.R. 417.532(a)(3) on reasonable cost reimbursement to health maintenance organizations (HMOs) and competitive medical plans (CMPs) is inconsistent with decisions of the Courts of Appeals for the Ninth and Eleventh Circuits, which have addressed absolute cost limits in other contexts. HCFA will, therefore, not apply the Part 417 absolute cost limit in determining whether HMO or CMP costs are reasonable and will promulgate an amendment to the Medicare regulations to conform those provisions to the court decisions.

**CITATIONS:** Sections 1861(v)(1)(A), 1871, 1876(h) of the Social Security Act (42 U.S.C. 1395x(v)(1)(A), 1395hh, 1395mm(h)); 42 C.F.R. section 417.532.

**PERTINENT HISTORY:** Section 114 of the Tax Equity and Fiscal Responsibility Act of 1982 amended section 1876 of the Social Security Act (the Act) to authorize two types of Medicare contracts with HMOs and CMPs: (1) "risk contracts," under which the organization is paid a pre-determined per capita rate of payment based on 95% of the Adjusted Average Per Capita Cost (AAPCC) to the Medicare program of providing covered services to beneficiaries who are not enrolled in HMOs or CMPs, and (2) "cost contracts," under which the organization is paid its "reasonable cost" of providing services to its enrolled Medicare beneficiaries. Section 1876(h)(1) specifies that payments under such cost contracts are based on the reasonable cost "as defined in section 1861(v)" of the Act.

Section 1861(v)(1)(A) in turn provides that the reasonable cost of any services

...shall be the cost actually incurred, excluding therefrom any part of incurred cost found to be unnecessary in the efficient delivery of needed health services, and shall be determined in accordance with regulations . . . [which] provide for the making of suitable retroactive corrective adjustments . . .

Like the provisions of section 1861(v)(1)(A) of the Act, which are applicable to costs incurred by Medicare providers, section 1876(h)(3) provides that payments to cost-contracting HMOs and CMPs

...shall be subject to appropriate retroactive corrective adjustment at the end of each contract year so as to assure that such organization is paid for the reasonable cost actually incurred (excluding any part of incurred cost found to be unnecessary in the efficient delivery of health services)....

Medicare regulations published in 1985 to implement the TEFRA provisions added the requirement that, effective with cost reports beginning on or after January 1, 1986, the AAPCC would constitute an absolute limit on the amount payable to a cost-contracting HMO and CMP. Specifically, 42 C.F.R. 417.532(a) provides that in addition to applying Medicare cost reimbursement principles,

...in judging whether costs are reasonable, HCFA applies the weighted average of the AAPCCs of each class of the organization's Medicare enrollees...for the organization's geographic area as an absolute limitation on the total amount payable.

As explained in the preamble to the final regulation, this rule was promulgated pursuant to the section 1861(v)(1)(A) authority to exclude costs found to be unnecessary in the efficient delivery of health services. See 50 FR 1329 (January 1, 1985). As promulgated, the rule provides for no exceptions.

Since the time that §417.532 of the regulations was promulgated, the courts have construed the authority to set cost limits under section 1861(v)(1)(A) to support generalized cost limits applied on a presumptive basis, but not absolute cost limits applied on a final or conclusive basis. See Medical Center Hospital v. Bowen, 839 F.2d 1504 (11th Cir. 1988); Regents of University of California v. Heckler, 771 F.2d 1182 (9th Cir. 1985). The courts have interpreted section 1861(v)(1)(A) as requiring that a Medicare provider be afforded an opportunity under the regulations to show that in its particular case, costs in excess of the applicable cost limits were reasonable and, therefore, reimbursable. The courts relied on the requirement for retroactive corrective adjustments, reasoning that this language precluded absolute limits. As shown above, this language appears in both sections 1861(v)(1)(A) and section 1876(h).

The cost limit regulation adopted under section 1861(v)(1)(A) that is applicable to Medicare providers (42 C.F.R. 413.30) includes an exceptions process, and we believe application of that regulation to be within our statutory authority. However, the regulation applicable to cost-contracting HMOs and CMPs under section

1876(h) of the Act imposes an absolute limit on reimbursement, without an exceptions process or criteria for evaluating whether costs in excess of the limit were in fact reasonable. We have, therefore, determined that section 417.532 of the regulations should be revised to assure that claims for reasonable costs incurred by HMOs or CMPs with cost contracts are not inappropriately denied. However, given the Supreme Court's decision that retroactive rulemaking is not authorized under the Medicare statute (Bowen v. Georgetown University Hospital, 109 S. Ct. 468 (1988)), any revised regulation could not affect cost reports that are currently pending.

We have made tentative settlement on HMOs' and CMPs' cost reports for periods beginning on or after January 1, 1986. We now determine that, in view of the adverse decisions of the Federal courts on the application of cost limits applicable to providers, until the regulations are revised, we will not apply the provisions of 42 C.F.R. 417.532(a)(3) in calculating the final amount of payments due cost-contracting HMOs or CMPs for periods beginning on or after January 1, 1986. Because any revisions in §417.532 would apply prospectively only, it would serve no purpose to delay final settlement of cost reports until after the revisions are promulgated. In reviewing cost reports of HMOs, HCFA may use area AAPCC levels as a guideline in evaluating whether further examination of specific cost reports is necessary to determine whether incurred costs are reasonable.

RULING: 42 C.F.R. 417.532(a)(3) is inconsistent with the interpretation adopted by the Federal courts with respect to HCFA's underlying statutory authority to impose cost limits. We will not apply the absolute cost limit contained in the regulation to cost reports submitted by Health Maintenance Organizations or Competitive Medical Plans under section 1876(h) of the Act. HCFA will initiate rulemaking procedures to conform §417.532 to the holdings of the Federal courts with respect to the establishment of Medicare cost limits under the authority of section 1861(v)(1)(A) of the Act.

DATED: 10/31/89



Louis B. Hays  
Acting Administrator  
Health Care Financing  
Administration



# **HCFA Rulings**

Department of Health

and Human Services

Health Care Financing

Administration

Ruling No. **HCFAR-89-2**

Date **OCTOBER 1989**

**HCFA Rulings** are decisions of the Administrator that serve as precedent final opinions and orders and statements of policy and interpretation. They provide clarification and interpretation of complex or ambiguous statutory or regulatory provisions relating to Medicare, Medicaid, Utilization and Quality Control Peer Review, and related matters.

**HCFA Rulings** are binding on all HCFA components, the Provider Reimbursement Review Board and Administrative Law Judges who hear Medicare appeals. These decisions promote consistency in interpretation of policy and adjudication of disputes.

This Ruling establishes that HCFA's application of the absolute limit provided in 42 CFR 417.532(a)(3) on reasonable cost reimbursement to health maintenance organizations and competitive medical plans is inconsistent with recent court of appeals decisions, which have addressed absolute cost limits in other Medicare contexts.



**MEDICARE PROGRAM**

**Health Maintenance Organizations and Competitive Medical Plans**

**Notice of Intent to Settle HMO and CMP Cost Reports for Periods Beginning on or after January 1, 1986, Without Application of Absolute Cost Limits.**

HCFAR 89-2

**PURPOSE:** This Ruling provides notice of the Health Care Financing Administration's (HCFA's) determination that application of the absolute limit provided in 42 C.F.R. 417.532(a)(3) on reasonable cost reimbursement to health maintenance organizations (HMOs) and competitive medical plans (CMPS) is inconsistent with decisions of the Courts of Appeals for the Ninth and Eleventh Circuits, which have addressed absolute cost limits in other contexts. HCFA will, therefore, not apply the Part 417 absolute cost limit in determining whether HMO or CMP costs are reasonable and will promulgate an amendment to the Medicare regulations to conform those provisions to the court decisions.

**CITATIONS:** Sections 1861(v)(1)(A), 1871, 1876(h) of the Social Security Act (42 U.S.C. 1395x(v)(1)(A), 1395hh, 1395mm(h)); 42 C.F.R. section 417.532.

**PERTINENT HISTORY:** Section 114 of the Tax Equity and Fiscal Responsibility Act of 1982 amended section 1876 of the Social Security Act (the Act) to authorize two types of Medicare contracts with HMOs and CMPS: (1) "risk contracts," under which the organization is paid a pre-determined per capita rate of payment based on 95% of the Adjusted Average Per Capita Cost (AAPCC) to the Medicare program of providing covered services to beneficiaries who are not enrolled in HMOs or CMPS, and (2) "cost contracts," under which the organization is paid its "reasonable cost" of providing services to its enrolled Medicare beneficiaries. Section 1876(h)(1) specifies that payments under such cost contracts are based on the reasonable cost "as defined in section 1861(v)" of the Act.

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...shall be the cost actually incurred, excluding therefrom any part of incurred cost found to be unnecessary in the efficient delivery of needed health services, and shall be determined in accordance with regulations . . . [which] provide for the making of suitable retroactive corrective adjustments ....

Like the provisions of section 1861(v)(1)(A) of the Act, which are applicable to costs incurred by Medicare providers, section 1876(h)(3) provides that payments to cost-contracting HMOs and CMPs

...shall be subject to appropriate retroactive corrective adjustment at the end of each contract year so as to assure that such organization is paid for the reasonable cost actually incurred (excluding any part of incurred cost found to be unnecessary in the efficient delivery of health services)....

Medicare regulations published in 1985 to implement the TEFRA provisions added the requirement that, effective with cost reports beginning on or after January 1, 1986, the AAPCC would constitute an absolute limit on the amount payable to a cost-contracting HMO and CMP. Specifically, 42 C.F.R. 417.532(a) provides that in addition to applying Medicare cost reimbursement principles,

...in judging whether costs are reasonable, HCFA applies the weighted average of the AAPCCs of each class of the organization's Medicare enrollees...for the organization's geographic area as an absolute limitation on the total amount payable.

As explained in the preamble to the final regulation, this rule was promulgated pursuant to the section 1861(v)(1)(A) authority to exclude costs found to be unnecessary in the efficient delivery of health services. See 50 FR 1329 (January 1, 1985). As promulgated, the rule provides for no exceptions.

Since the time that §417.532 of the regulations was promulgated, the courts have construed the authority to set cost limits under section 1861(v)(1)(A) to support generalized cost limits applied on a presumptive basis, but not absolute cost limits applied on a final or conclusive basis. See Medical Center Hospital v. Bowen, 839 F.2d 1504 (11th Cir. 1988); Regents of University of California v. Heckler, 771 F.2d 1182 (9th Cir. 1985). The courts have interpreted section 1861(v)(1)(A) as requiring that a Medicare provider be afforded an opportunity under the regulations to show that in its particular case, costs in excess of the applicable cost limits were reasonable and, therefore, reimbursable. The courts relied on the requirement for retroactive corrective adjustments, reasoning that this language precluded absolute limits. As shown above, this language appears in both sections 1861(v)(1)(A) and section 1876(h).

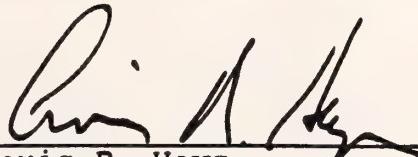
The cost limit regulation adopted under section 1861(v)(1)(A) that is applicable to Medicare providers (42 C.F.R. 413.30) includes an exceptions process, and we believe application of that regulation to be within our statutory authority. However, the regulation applicable to cost-contracting HMOs and CMPs under section

1876(h) of the Act imposes an absolute limit on reimbursement, without an exceptions process or criteria for evaluating whether costs in excess of the limit were in fact reasonable. We have, therefore, determined that section 417.532 of the regulations should be revised to assure that claims for reasonable costs incurred by HMOs or CMPs with cost contracts are not inappropriately denied. However, given the Supreme Court's decision that retroactive rulemaking is not authorized under the Medicare statute (Bowen v. Georgetown University Hospital, 109 S. Ct. 468 (1988)), any revised regulation could not affect cost reports that are currently pending.

We have made tentative settlement on HMOs' and CMPs' cost reports for periods beginning on or after January 1, 1986. We now determine that, in view of the adverse decisions of the Federal courts on the application of cost limits applicable to providers, until the regulations are revised, we will not apply the provisions of 42 C.F.R. 417.532(a)(3) in calculating the final amount of payments due cost-contracting HMOs or CMPs for periods beginning on or after January 1, 1986. Because any revisions in §417.532 would apply prospectively only, it would serve no purpose to delay final settlement of cost reports until after the revisions are promulgated. In reviewing cost reports of HMOs, HCFA may use area AAPCC levels as a guideline in evaluating whether further examination of specific cost reports is necessary to determine whether incurred costs are reasonable.

RULING: 42 C.F.R. 417.532(a)(3) is inconsistent with the interpretation adopted by the Federal courts with respect to HCFA's underlying statutory authority to impose cost limits. We will not apply the absolute cost limit contained in the regulation to cost reports submitted by Health Maintenance Organizations or Competitive Medical Plans under section 1876(h) of the Act. HCFA will initiate rulemaking procedures to conform §417.532 to the holdings of the Federal courts with respect to the establishment of Medicare cost limits under the authority of section 1861(v)(1)(A) of the Act.

DATED: 10/31/89



Louis B. Hays  
Acting Administrator  
Health Care Financing  
Administration

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# HCFA Rulings

Department of Health  
and Human Services

Health Care Financing  
Administration

Ruling No. HC FAR-89-2

Date OCTOBER 1989

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**MEDICARE PROGRAM**

**Health Maintenance Organizations and Competitive Medical Plans**

**Notice of Intent to Settle HMO and CMP Cost Reports for Periods Beginning on or after January 1, 1986, Without Application of Absolute Cost Limits.**

HCFAR 89-2

**PURPOSE:** This Ruling provides notice of the Health Care Financing Administration's (HCFA's) determination that application of the absolute limit provided in 42 C.F.R. 417.532(a)(3) on reasonable cost reimbursement to health maintenance organizations (HMOs) and competitive medical plans (CMPs) is inconsistent with decisions of the Courts of Appeals for the Ninth and Eleventh Circuits, which have addressed absolute cost limits in other contexts. HCFA will, therefore, not apply the Part 417 absolute cost limit in determining whether HMO or CMP costs are reasonable and will promulgate an amendment to the Medicare regulations to conform those provisions to the court decisions.

**CITATIONS:** Sections 1861(v)(1)(A), 1871, 1876(h) of the Social Security Act (42 U.S.C. 1395x(v)(1)(A), 1395hh, 1395mm(h)); 42 C.F.R. section 417.532.

**PERTINENT HISTORY:** Section 114 of the Tax Equity and Fiscal Responsibility Act of 1982 amended section 1876 of the Social Security Act (the Act) to authorize two types of Medicare contracts with HMOs and CMPs: (1) "risk contracts," under which the organization is paid a pre-determined per capita rate of payment based on 95% of the Adjusted Average Per Capita Cost (AAPCC) to the Medicare program of providing covered services to beneficiaries who are not enrolled in HMOs or CMPs, and (2) "cost contracts," under which the organization is paid its "reasonable cost" of providing services to its enrolled Medicare beneficiaries. Section 1876(h)(1) specifies that payments under such cost contracts are based on the reasonable cost "as defined in section 1861(v)" of the Act.

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Since the time that §417.532 of the regulations was promulgated, the courts have construed the authority to set cost limits under section 1861(v)(1)(A) to support generalized cost limits applied on a presumptive basis, but not absolute cost limits applied on a final or conclusive basis. See Medical Center Hospital v. Bowen, 839 F.2d 1504 (11th Cir. 1988); Regents of University of California v. Heckler, 771 F.2d 1182 (9th Cir. 1985). The courts have interpreted section 1861(v)(1)(A) as requiring that a Medicare provider be afforded an opportunity under the regulations to show that in its particular case, costs in excess of the applicable cost limits were reasonable and, therefore, reimbursable. The courts relied on the requirement for retroactive corrective adjustments, reasoning that this language precluded absolute limits. As shown above, this language appears in both sections 1861(v)(1)(A) and section 1876(h).

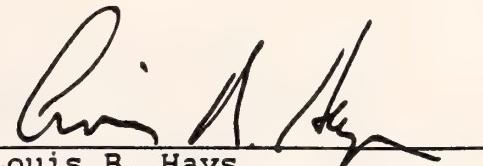
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We have made tentative settlement on HMOs' and CMPs' cost reports for periods beginning on or after January 1, 1986. We now determine that, in view of the adverse decisions of the Federal courts on the application of cost limits applicable to providers, until the regulations are revised, we will not apply the provisions of 42 C.F.R. 417.532(a)(3) in calculating the final amount of payments due cost-contracting HMOs or CMPs for periods beginning on or after January 1, 1986. Because any revisions in §417.532 would apply prospectively only, it would serve no purpose to delay final settlement of cost reports until after the revisions are promulgated. In reviewing cost reports of HMOs, HCFA may use area AAPCC levels as a guideline in evaluating whether further examination of specific cost reports is necessary to determine whether incurred costs are reasonable.

RULING: 42 C.F.R. 417.532(a)(3) is inconsistent with the interpretation adopted by the Federal courts with respect to HCFA's underlying statutory authority to impose cost limits. We will not apply the absolute cost limit contained in the regulation to cost reports submitted by Health Maintenance Organizations or Competitive Medical Plans under section 1876(h) of the Act. HCFA will initiate rulemaking procedures to conform §417.532 to the holdings of the Federal courts with respect to the establishment of Medicare cost limits under the authority of section 1861(v)(1)(A) of the Act.

DATED: 10/31/89



Louis B. Hays  
Acting Administrator  
Health Care Financing  
Administration

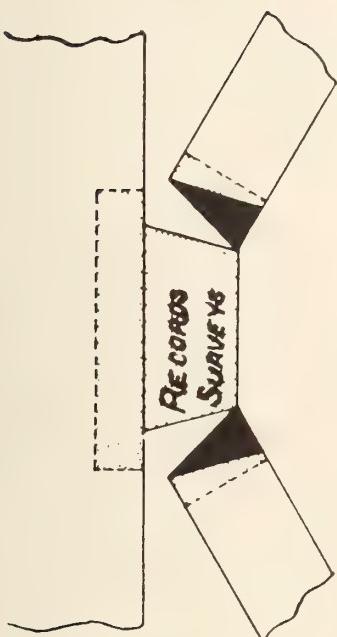


How to use these separators

Look for your reference letter. The far left column designated "TAB" will indicate proper tab position for that number or letter. Cut off and discard all tabs except the one you wish to retain. Example: Position number "10" would be found behind the fourth tab. Position letter "C" would be found behind the third tab.

TAB	(CHOOSE YOUR TAB)			
FIRST	V	O	H	A
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# HCFA Rulings

Department of Health  
and Human Services

Health Care Financing  
Administration

Ruling No. HCFAR 89-1

Date January 1989

**HCFA Rulings** are decisions of the Administrator that serve as precedent final opinions and orders and statements of policy and interpretation. They provide clarification and interpretation of complex or ambiguous statutory or regulatory provisions relating to Medicare, Medicaid, Utilization and Quality Control Peer Review, and related matters.

**HCFA Rulings** are binding on all HCFA components, the Provider Reimbursement Review Board and Administrative Law Judges who hear Medicare appeals. These decisions promote consistency in interpretation of policy and adjudication of disputes.

This Ruling establishes that two recent U.S. Supreme Court decisions control and therefore render moot for lack of an actual case or controversy various claims and appeals challenging certain Medicare reimbursement regulations that are now pending before fiscal intermediaries, the Provider Reimbursement Review Board, HCFA and in the federal courts. It also explains how HCFA and its fiscal intermediaries will make payment in pending administrative and judicial appeals that are controlled by these two court decisions.

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MEDICARE PROGRAM

Hospital Insurance and Supplementary Medical Insurance Benefits (Parts A and B)

Notice of Controlling Adverse Decisions by the Supreme Court and the D.C. Circuit Court of Appeals, and Corresponding Requirement of Remand to the Intermediaries for Payment of Certain Pending Moot Administrative Appeals Challenging the 1981 and 1984 Medicare Wage Index Rules; the 1979 and 1986 Medicare Malpractice Rules; and the Hospital-Specific Rate Under PPS

PURPOSE: This Ruling provides notice of the determination of the Health Care Financing Administration (HCFA) that two recent decisions issued respectively by the United States Supreme Court in Bowen v. Georgetown University Hospital, \_\_\_\_ U. S. \_\_\_\_, 109 S. Ct. 468 (1988) ("Georgetown I"), and the United States Court of Appeals for the District of Columbia Circuit in Georgetown University Hospital v. Bowen, 862 F. 2d 323 (D.C. Cir. 1988) ("Georgetown II"), control and thereby render moot for lack of an actual case or controversy various claims and appeals challenging certain Medicare reimbursement regulations that are now pending before the fiscal intermediaries, the Provider Reimbursement Review Board (PRRB), HCFA and in the federal courts. This Ruling also explains how HCFA and its fiscal intermediaries will make payment in pending administrative and judicial appeals that are controlled by these two court decisions,

these two court decisions, including an explanation of how appeals pending at various administrative levels should be processed.

CITATIONS: Sections 1861(v)(1)(A), 1871, and 1886(b)(3)(A) and (d) of the Social Security Act (42 U.S.C. 1395x(v)(1)(A), 1395hh, and 1395ww(b)(3)(A) and (d)); 42 C.F.R. 412.72(a)(3), 412.72(b), 413.53(a)(1)(i), 413.56; 46 FR 33637 (June 30, 1981); 49 FR 46495 (Nov. 26, 1984).

PERTINENT HISTORY:

Hospital Cost Limits -- For inpatient hospital services furnished in cost reporting periods beginning before October 1, 1983, the provider is entitled to payment of the lesser of the reasonable cost or the customary charges for services it furnishes to Medicare beneficiaries. 42 U.S.C. 1395f(b)(1). The statutory definition of reasonable cost, 42 U.S.C. 1395x(v)(1)(A), authorizes the Secretary to promulgate "regulations establishing the method or methods to be used, and the items to be included, in determining such costs." Pursuant to statutory authority, the Secretary has adopted a cost limits regulation, 42 C.F.R. 413.30, and specific schedules of cost limits, in addition to issuing cost apportionment regulations, 42 C.F.R. 413.50-413.56.

In 1981, the Secretary eliminated federal government hospital wage data from the wage index component of the schedule of cost limits for hospital routine inpatient service costs. 46 FR 33637 and 33638-40 (June 30, 1981) ("the 1981 cost limits"). In 1983, a district court declared invalid for lack of compliance with the notice and comment requirements of the Administrative Procedure Act (APA), 5 U.S.C. 551 et seq., the wage index component of the 1981 cost limits. District of Columbia Hospital Ass'n v. Heckler, No. 82-2520 (D.D.C. April 29, 1983). After later providing notice and opportunity for public comment, the same wage index rule was reissued in 1984 and applied retroactively to the 1981 cost limits. 49 FR 46495 (Nov. 26, 1984) ("the retroactive 1984 wage index rule"). On December 12, 1988, the Supreme Court held that the retroactive 1984 wage index rule is not authorized by the rulemaking authority included in the statutory definition of reasonable cost, 42 U.S.C. 1395x(v)(1)(A), or by the Secretary's general authority to issue regulations necessary to implement the Medicare program, id. at 405(a), 1395hh, and 1395ii. Georgetown I, supra.

Malpractice Insurance Costs--For cost reporting periods beginning prior to July 1, 1979, provider malpractice

insurance costs (i.e., the cost of a malpractice insurance policy or of contributions made to a self-insurance fund) were reimbursed in accordance with the pre-1979 utilization method, which required, first, that malpractice insurance costs be included in the general and administrative cost center (G&A pool) along with other provider overhead costs and, second, that insurance costs be apportioned to the Medicare program in accordance with the provider's Medicare patient utilization rate. See 51 FR 11142-43 (April 1, 1986). See also 42 C.F.R. 405.452(b)(1), redesignated as 42 C.F.R. 413.53(a)(1)(i). In 1979, the Secretary determined that it was necessary and appropriate to remove malpractice insurance costs from the G&A pool and reimburse those costs in accordance with the 1979 malpractice rule, which, for cost reporting periods beginning on or after July 1, 1979, directly apportioned a provider's insurance costs based on the ratio of malpractice losses paid to Medicare patients compared to losses paid to all patients. See 51 FR 11143. See also 44 FR 31641 (June 1, 1979), adding 42 C.F.R. 405.452(b)(1)(ii), redesignated as 42 C.F.R. 405.452(a)(1)(ii) (48 FR 39811 (Sept. 1, 1983)). In 1986, in response to litigation challenging the 1979 malpractice rule (see Tallahassee Memorial Regional Medical Center v. Bowen, 815 F.2d 1435, 1441 n.7 (11th Cir. 1987), cert.

denied, 108 S.Ct. 1573 (1988) (collecting cases)), and the availability of new data, the Secretary promulgated "the 1986 malpractice rule," which, effective May 1, 1986, eliminated the 1979 malpractice rule and established a new methodology for apportioning provider malpractice insurance costs that is based in large part on the provider's Medicare utilization rate. See 51 FR 11142 and 11195-96, adding 42 C.F.R. 405.457 (April 1, 1986), redesignated as 42 C.F.R. 413.56 (51 FR 34790 and 34808-9 (Sept. 30, 1986)). The 1986 malpractice rule applies, subject to the Medicare program's general rules of administrative finality and reopening, to cost reporting periods beginning on or after July 1, 1979. 42 C.F.R. 413.56(a).

Although the Supreme Court's decision in Georgetown I literally applies only to the retroactive 1984 wage index rule, HCFA has determined that it also controls properly pending administrative and judicial appeals challenging the 1986 malpractice rule, 42 C.F.R. 413.56, for cost reporting periods beginning before the May 1, 1986 effective date of the 1986 regulation. In invalidating the retroactive 1984 wage index rule, the Supreme Court specifically rejected the agency's contention that, in addition to the Secretary's general rulemaking authority

under 42 U.S.C. 1395x(v)(1)(A) and 1395hh, clause (ii) of 42 U.S.C. 1395x(v)(1)(A) authorizes retroactive rulemaking. Georgetown I, supra, 57 U.S.L.W. at 4059-60. Because retroactive application of the 1986 malpractice rule was expressly based on 42 U.S.C. 1395x(v)(1)(A)(ii) and 1395hh (see 51 FR at 11184-87), HCFA has concluded that the Supreme Court's decision also controls properly pending, not otherwise settled, challenges to retroactive application of the 1986 regulation.

In accordance with the foregoing determination, HCFA will extend the basic holding and application of the Georgetown I decision to all properly pending, and not otherwise settled, appeals challenging the wage index component of the 1981 cost limits and the retroactive 1984 Medicare wage index rule and to the application of the 1979 and 1986 Medicare malpractice rules to cost reporting periods beginning before May 1, 1986. Accordingly, HCFA is instructing its fiscal intermediaries to allow properly pending, not otherwise settled, hospital reimbursement claims for malpractice insurance costs for cost reporting periods beginning before May 1, 1986 under the pre-1979 utilization method, 42 C.F.R. 405.452(b)(1).

HCFA's action eliminates any actual case or controversy and thereby renders moot all pending appeals challenging

the 1986 malpractice rule for cost reporting periods beginning before May 1, 1986, provided that such appeals satisfy the jurisdictional requirements of 42 U.S.C. 1395oo, and provided further that the hospital did not accept the May 11, 1988 "HHS Settlement Offer -- Medicare Malpractice Insurance Costs Litigation," or otherwise settle. HCFA is taking the steps necessary to secure a remand from the federal courts to the agency of the above-described wage index and malpractice insurance cost reimbursement challenges for payment. As explained below, similar measures are being undertaken to enable payment of reimbursement claims pending before the Deputy Administrator of HCFA, the PRRB, and the intermediaries that are controlled by the Georgetown I decision.

Prospective Payment System: Hospital-Specific Rate -- For cost reporting periods beginning on or after October 1, 1983, the Medicare program's prospective payment system (PPS) provides that, after a four-year transition period, a hospital's entire payment for the operating cost of inpatient services will, with several exceptions, be based on a predetermined nationally applicable rate for each patient discharge, according to which of numerous specified diagnosis related groups (DRGs) best characterizes the patient's diagnosis and treatment. See 42 U.S.C. 1395ww(d); 42 C.F.R. Part 412. During the

transition period, an increasing proportion of a hospital's PPS payment is based on the federal rate, and a declining proportion of its payment for each discharge is based on the provider's historical costs (the hospital-specific or HSP rate). Id.

The hospital-specific rate is derived from the historical costs that a hospital incurred in its base year under the cost-based reimbursement system. 42 C.F.R. 412.71. See also 42 U.S.C. 1395ww(b)(3)(A) and 1395ww(d)(1)(A) and (C). The fiscal intermediaries were responsible for calculating the hospital-specific rate prior to the beginning of each hospital's first PPS year, by estimating the reasonable cost otherwise reimbursable for the base year itself, and then making specified modifications to arrive at the hospital-specific rate. See 42 C.F.R. 412.71 and 412.72.

Given that reimbursement amounts in the base year are potentially subject to revision through administrative action and judicial review, the PPS regulations address the consequences of such revisions for the HSP rate. The Secretary's prospective relief rule, 42 C.F.R. 412.72(a)(3), authorizes, as a matter of administrative discretion, automatic prospective adjustments to the HSP

rate to take account of the recognition of additional base year costs in a final judicial decision or as the result of various administrative actions. However, retrospective changes are permitted only if the hospital can establish that the original estimation of base year costs was "unreasonable and clearly erroneous in light of the data available at the time the estimation was made." 42 C.F.R. 412.72(b)(2).

On November 15, 1988, the United States Court of Appeals for the District of Columbia Circuit held in Georgetown II, supra, that when a provider secures a final court judgment on a legal challenge brought under the prior cost-based reimbursement system, the agency must give full effect to such judgments throughout the four-year transition period under PPS. The Court rejected the principles and procedures established by the Medicare regulations, which authorize automatic prospective adjustments to the hospital-specific rate to reflect newly recognized base year costs but permit retrospective relief only under limited circumstances.

The Government has decided not to file a petition for certiorari in the Georgetown II case. Instead, HCFA

acquiesces on a nationwide basis in the D.C. Circuit's decision, to the extent that the statutory requirements, 42 U.S.C. 1395oo, for administrative and judicial appeals are satisfied with respect to the provider's challenge to the hospital-specific rate under PPS, and where such HSP rate challenge is predicated on certain factors (described below) that pertain to the hospital's base year costs. Accordingly, HCFA is instructing the intermediaries to adjust the HSP rate throughout the four-year transition period to reflect a hospital's additional base year costs that are newly recognized as the result of these enumerated factors. (Similarly, HCFA is instructing its intermediaries to adjust downward the HSP rate to reflect any subsequently determined decrease in a hospital's base year costs.) Separate settlements such as may be made under the May 11, 1988 "HHS Settlement Offer -- Medicare Malpractice Insurance Costs Litigation," will, of course, be controlled by their own terms and will not be affected by the Georgetown I decision or by HCFA's nationwide acquiescence in the Georgetown II decision.

HCFA's nationwide acquiescence in the Georgetown II decision renders moot for lack of an actual case or controversy all pending (and not otherwise settled HSP rate) appeals that, first, satisfy the jurisdictional requirements imposed by 42 U.S.C. 1395oo

and that, second, request that the HSP rate be revised retroactively (or for the duration of the four-year transition period) to reflect additional base year costs that are (or will be) newly recognized as the result of: a final, nonappealable court judgment; the administrative actions identified in 42 C.F.R. 412.72(a)(3)(i); pending claims for reimbursement under the pre-1981 wage index component of the 1981 cost limits; or pending malpractice insurance cost reimbursement claims under the pre-1979 utilization method of a hospital that did not accept the May 11, 1988 "HHS Settlement Offer -- Medicare Malpractice Insurance Costs Litigation." HCFA is undertaking appropriate measures in the federal courts to have the above-described challenges to the HSP rate remanded to the agency for payment. Similar steps are being taken to achieve payment of reimbursement claims pending before the Deputy Administrator of HCFA, the PRRB, and the intermediaries that are controlled by HCFA's nationwide acquiescence in the Georgetown II decision.

IMPLEMENTATION: In order to resolve in an orderly manner pending administrative appeals that have been rendered moot by the Georgetown I and Georgetown II decisions and to facilitate payment of affected reimbursement claims (described above), the administrative tribunal (i.e., the

intermediary, the PRRB, or the Deputy Administrator of HCFA) before which such appeal is pending shall, first, determine whether the appeal satisfies the jurisdictional prerequisites imposed by 42 U.S.C. 1395oo; and, second, if the applicable jurisdictional requirements are satisfied, then a determination shall be made that the provider is entitled to payment of its reimbursement claims under the terms of this Ruling. In the event such a favorable determination is made in an appeal pending before the PRRB or the Deputy Administrator of HCFA, the appeal shall be remanded to the appropriate intermediary for payment.

HCFA recognizes that, given the substantial number of wage index, malpractice insurance cost, and HSP rate reimbursement appeals pending at the PRRB, it could be difficult for the PRRB to identify and decide which of the pending administrative appeals of these issues would be controlled by the Georgetown I and Georgetown II decisions, and also meet the jurisdictional requirements of 42 U.S.C. 1395oo. Thus, HCFA is authorizing an alternative procedure in order to facilitate the orderly disposition of wage index, malpractice insurance cost, and HSP rate reimbursement administrative appeals and to avoid any inordinate delay.

Under this alternative procedure, the provider may request the PRRB to remand a pending appeal of the above-described wage index, malpractice insurance cost, or HSP rate reimbursement issues to the intermediary for payment of the provider's reimbursement claims prior to the time that the PRRB determines whether the provider's reimbursement claims are controlled by the Georgetown I or Georgetown II decisions and whether such claims satisfy the jurisdictional requirements imposed by 42 U.S.C. 1395oo. The intermediary would assume, under this alternative procedure, the initial responsibility of determining whether the provider satisfied the jurisdictional requirements, 42 U.S.C. 1395oo, for appealing its reimbursement claims to the PRRB, and whether the provider is entitled to payment under this Ruling. If the provider is dissatisfied with the intermediary's determination under this alternative procedure that the provider failed to satisfy the applicable jurisdictional requirements or that it otherwise failed to qualify for payment under the terms of this Ruling, then it may resume its original PRRB appeal without prejudice.

RULING: It is HCFA's Ruling that the Supreme Court's decision in Georgetown I, supra, 109 S. Ct. 468 (1988) controls and thereby renders moot for lack of an actual

of an actual case or controversy appeals challenging the wage index component of the 1981 cost limits or the retroactive 1984 wage index rule, in addition to appeals challenging the 1979 malpractice rule or the 1986 malpractice rule for cost reporting periods beginning before May 1, 1986, provided that such appeals satisfy the jurisdictional requirements of 42 U.S.C. 1395oo, and provided further that the hospital did not accept the May 11, 1988 "HHS Settlement Offer -- Medicare Malpractice Insurance Costs Litigation," or otherwise settle.

Furthermore, it is HCFA's Ruling that the D.C. Circuit's decision in Georgetown II, supra, Nos. 88-5026 and 88-5040 (D.C. Cir. Nov. 15, 1988) controls and thereby renders moot for lack of an actual case or controversy all pending (and not otherwise settled HSP rate) appeals that, first, satisfy the jurisdictional requirements imposed by 42 U.S.C. 1395oo and that, second, request that the HSP rate be revised retroactively (or for the duration of the four-year transition period) to reflect additional base year costs that are (or will be) newly recognized as the result of: a final, nonappealable court judgment; the administrative actions identified in 42 C.F.R. 412.72(a)(3)(i); pending claims for reimbursement under the pre-1981 wage index component of the 1981 cost limits;

or pending malpractice insurance cost reimbursement claims under the pre-1979 utilization method of a hospital that did not accept the May 11, 1988 "HHS Settlement Offer -- Medicare Malpractice Insurance Costs Litigation."

Finally, it is HCFA's Ruling that in order to ensure that the foregoing Rulings will be implemented in an expeditious and orderly manner with respect to pending appeals in the federal courts of the above-described wage index, malpractice insurance cost, or HSP rate reimbursement issues, HCFA will take appropriate measures in the federal courts to obtain a remand to the agency for payment, or, as may be necessary, for further jurisdictional findings by the administrative tribunal. Similarly, it is HCFA's Ruling that for any claim or appeal of the above-described wage index, malpractice insurance cost, or HSP rate reimbursement issues that is pending administratively (i.e., before the Deputy Administrator of HCFA, the PRRB, or the intermediary) that administrative tribunal shall, first, determine whether the appeal satisfies the jurisdictional prerequisites, 42 U.S.C. §1395oo, and, second, if the applicable jurisdictional requirements are satisfied, then a determination shall be made that the provider is entitled to payment of its reimbursement claims under the terms of

this Ruling. In the event such a favorable determination is made in an appeal pending before the PRRB or the Deputy Administrator of HCFA, the case shall be remanded to the appropriate intermediary for payment. Moreover, in order to provide an alternative means by which the provider may avoid the possibility of delay before the PRRB and to facilitate prompt payment of reimbursement claims subject to this Ruling, it is also HCFA's Ruling that if the provider requests the PRRB to remand to the intermediary for payment pursuant to this Ruling, an appeal of the above-described wage index, malpractice insurance cost, or HSP rate reimbursement issues -- before the PRRB has determined whether the appeal satisfied the jurisdictional requirements of 42 U.S.C. 1395oo and whether the provider's reimbursement claims are governed by this Ruling -- then the intermediary shall not oppose the provider's motion; the PRRB shall grant the provider's motion; and the intermediary shall make, subject to a determination as to whether the provider satisfies the applicable jurisdictional requirements and otherwise satisfies the terms of this Ruling, appropriate payments. However, if the intermediary ultimately determines that the provider failed to satisfy the jurisdictional prerequisites imposed by 42 U.S.C. 1395oo or otherwise

failed to qualify for payment pursuant to this Ruling, then the PRRB shall permit the provider to resume its original administrative appeal without prejudice.

EFFECTIVE DATE

This Ruling is effective January 26<sup>th</sup>, 1989.

DATED: 1.26.89



William L. Roper, MD  
Administrator, Health  
Care Financing Admini-  
stration



NOTE

No HCFA Rulings were published in 1988



# HCFA Rulings

Department of Health  
and Human Services

Health Care Financing  
Administration

Ruling No. HCFAR 89-1

Date January 1989

*July 1989*

**HCFA Rulings** are decisions of the Administrator that serve as precedent final opinions and orders and statements of policy and interpretation. They provide clarification and interpretation of complex or ambiguous statutory or regulatory provisions relating to Medicare, Medicaid, Utilization and Quality Control Peer Review, and related matters.

**HCFA Rulings** are binding on all HCFA components, the Provider Reimbursement Review Board and Administrative Law Judges who hear Medicare appeals. These decisions promote consistency in interpretation of policy and adjudication of disputes.

This Ruling establishes that two recent U.S. Supreme Court decisions control and therefore render moot for lack of an actual case or controversy various claims and appeals challenging certain Medicare reimbursement regulations that are now pending before fiscal intermediaries, the Provider Reimbursement Review Board, HCFA and in the federal courts. It also explains how HCFA and its fiscal intermediaries will make payment in pending administrative and judicial appeals that are controlled by these two court decisions.



MEDICARE PROGRAM

Hospital Insurance and Supplementary Medical Insurance Benefits (Parts A and B)

Notice of Controlling Adverse Decisions by the Supreme Court and the D.C. Circuit Court of Appeals, and Corresponding Requirement of Remand to the Intermediaries for Payment of Certain Pending Moot Administrative Appeals Challenging the 1981 and 1984 Medicare Wage Index Rules; the 1979 and 1986 Medicare Malpractice Rules; and the Hospital-Specific Rate Under PPS

PURPOSE: This Ruling provides notice of the determination of the Health Care Financing Administration (HCFA) that two recent decisions issued respectively by the United States Supreme Court in Bowen v. Georgetown University Hospital, \_\_\_\_ U. S. \_\_\_\_, 109 S. Ct. 468 (1988) ("Georgetown I"), and the United States Court of Appeals for the District of Columbia Circuit in Georgetown University Hospital v. Bowen, 862 F. 2d 323 (D.C. Cir. 1988) ("Georgetown II"), control and thereby render moot for lack of an actual case or controversy various claims and appeals challenging certain Medicare reimbursement regulations that are now pending before the fiscal intermediaries, the Provider Reimbursement Review Board (PRRB), HCFA and in the federal courts. This Ruling also explains how HCFA and its fiscal intermediaries will make payment in pending administrative and judicial appeals that are controlled by these two court decisions,

these two court decisions, including an explanation of how appeals pending at various administrative levels should be processed.

CITATIONS: Sections 1861(v)(1)(A), 1871, and 1886(b)(3)(A) and (d) of the Social Security Act (42 U.S.C. 1395x(v)(1)(A), 1395hh, and 1395ww(b)(3)(A) and (d)); 42 C.F.R. 412.72(a)(3), 412.72(b), 413.53(a)(1)(i), 413.56; 46 FR 33637 (June 30, 1981); 49 FR 46495 (Nov. 26, 1984).

PERTINENT HISTORY:

Hospital Cost Limits -- For inpatient hospital services furnished in cost reporting periods beginning before October 1, 1983, the provider is entitled to payment of the lesser of the reasonable cost or the customary charges for services it furnishes to Medicare beneficiaries. 42 U.S.C. 1395f(b)(1). The statutory definition of reasonable cost, 42 U.S.C. 1395x(v)(1)(A), authorizes the Secretary to promulgate "regulations establishing the method or methods to be used, and the items to be included, in determining such costs." Pursuant to statutory authority, the Secretary has adopted a cost limits regulation, 42 C.F.R. 413.30, and specific schedules of cost limits, in addition to issuing cost apportionment regulations, 42 C.F.R. 413.50-413.56.

In 1981, the Secretary eliminated federal government hospital wage data from the wage index component of the schedule of cost limits for hospital routine inpatient service costs. 46 FR 33637 and 33638-40 (June 30, 1981) ("the 1981 cost limits"). In 1983, a district court declared invalid for lack of compliance with the notice and comment requirements of the Administrative Procedure Act (APA), 5 U.S.C. 551 et seq., the wage index component of the 1981 cost limits. District of Columbia Hospital Ass'n v. Heckler, No. 82-2520 (D.D.C. April 29, 1983). After later providing notice and opportunity for public comment, the same wage index rule was reissued in 1984 and applied retroactively to the 1981 cost limits. 49 FR 46495 (Nov. 26, 1984) ("the retroactive 1984 wage index rule"). On December 12, 1988, the Supreme Court held that the retroactive 1984 wage index rule is not authorized by the rulemaking authority included in the statutory definition of reasonable cost, 42 U.S.C. 1395x(v)(1)(A), or by the Secretary's general authority to issue regulations necessary to implement the Medicare program, id. at 405(a), 1395hh, and 1395ii. Georgetown I, supra.

Malpractice Insurance Costs--For cost reporting periods beginning prior to July 1, 1979, provider malpractice

insurance costs (i.e., the cost of a malpractice insurance policy or of contributions made to a self-insurance fund) were reimbursed in accordance with the pre-1979 utilization method, which required, first, that malpractice insurance costs be included in the general and administrative cost center (G&A pool) along with other provider overhead costs and, second, that insurance costs be apportioned to the Medicare program in accordance with the provider's Medicare patient utilization rate. See 51 FR 11142-43 (April 1, 1986). See also 42 C.F.R. 405.452(b)(1), redesignated as 42 C.F.R. 413.53(a)(1)(i). In 1979, the Secretary determined that it was necessary and appropriate to remove malpractice insurance costs from the G&A pool and reimburse those costs in accordance with the 1979 malpractice rule, which, for cost reporting periods beginning on or after July 1, 1979, directly apportioned a provider's insurance costs based on the ratio of malpractice losses paid to Medicare patients compared to losses paid to all patients. See 51 FR 11143. See also 44 FR 31641 (June 1, 1979), adding 42 C.F.R. 405.452(b)(1)(ii), redesignated as 42 C.F.R. 405.452(a)(1)(ii) (48 FR 39811 (Sept. 1, 1983)). In 1986, in response to litigation challenging the 1979 malpractice rule (see Tallahassee Memorial Regional Medical Center v. Bowen, 815 F.2d 1435, 1441 n.7 (11th Cir. 1987), cert.

denied, 108 S.Ct. 1573 (1988) (collecting cases)), and the availability of new data, the Secretary promulgated "the 1986 malpractice rule," which, effective May 1, 1986, eliminated the 1979 malpractice rule and established a new methodology for apportioning provider malpractice insurance costs that is based in large part on the provider's Medicare utilization rate. See 51 FR 11142 and 11195-96, adding 42 C.F.R. 405.457 (April 1, 1986), redesignated as 42 C.F.R. 413.56 (51 FR 34790 and 34808-9 (Sept. 30, 1986)). The 1986 malpractice rule applies, subject to the Medicare program's general rules of administrative finality and reopening, to cost reporting periods beginning on or after July 1, 1979. 42 C.F.R. 413.56(a).

Although the Supreme Court's decision in Georgetown I literally applies only to the retroactive 1984 wage index rule, HCFA has determined that it also controls properly pending administrative and judicial appeals challenging the 1986 malpractice rule, 42 C.F.R. 413.56, for cost reporting periods beginning before the May 1, 1986 effective date of the 1986 regulation. In invalidating the retroactive 1984 wage index rule, the Supreme Court specifically rejected the agency's contention that, in addition to the Secretary's general rulemaking authority

under 42 U.S.C. 1395x(v)(1)(A) and 1395hh, clause (ii) of 42 U.S.C. 1395x(v)(1)(A) authorizes retroactive rulemaking. Georgetown I, supra, 57 U.S.L.W. at 4059-60. Because retroactive application of the 1986 malpractice rule was expressly based on 42 U.S.C. 1395x(v)(1)(A)(ii) and 1395hh (see 51 FR at 11184-87), HCFA has concluded that the Supreme Court's decision also controls properly pending, not otherwise settled, challenges to retroactive application of the 1986 regulation.

In accordance with the foregoing determination, HCFA will extend the basic holding and application of the Georgetown I decision to all properly pending, and not otherwise settled, appeals challenging the wage index component of the 1981 cost limits and the retroactive 1984 Medicare wage index rule and to the application of the 1979 and 1986 Medicare malpractice rules to cost reporting periods beginning before May 1, 1986. Accordingly, HCFA is instructing its fiscal intermediaries to allow properly pending, not otherwise settled, hospital reimbursement claims for malpractice insurance costs for cost reporting periods beginning before May 1, 1986 under the pre-1979 utilization method, 42 C.F.R. 405.452(b)(1).

HCFA's action eliminates any actual case or controversy and thereby renders moot all pending appeals challenging

the 1986 malpractice rule for cost reporting periods beginning before May 1, 1986, provided that such appeals satisfy the jurisdictional requirements of 42 U.S.C. 1395oo, and provided further that the hospital did not accept the May 11, 1988 "HHS Settlement Offer -- Medicare Malpractice Insurance Costs Litigation," or otherwise settle. HCFA is taking the steps necessary to secure a remand from the federal courts to the agency of the above-described wage index and malpractice insurance cost reimbursement challenges for payment. As explained below, similar measures are being undertaken to enable payment of reimbursement claims pending before the Deputy Administrator of HCFA, the PRRB, and the intermediaries that are controlled by the Georgetown I decision.

Prospective Payment System: Hospital-Specific Rate -- For cost reporting periods beginning on or after October 1, 1983, the Medicare program's prospective payment system (PPS) provides that, after a four-year transition period, a hospital's entire payment for the operating cost of inpatient services will, with several exceptions, be based on a predetermined nationally applicable rate for each patient discharge, according to which of numerous specified diagnosis related groups (DRGs) best characterizes the patient's diagnosis and treatment. See 42 U.S.C. 1395ww(d); 42 C.F.R. Part 412. During the

transition period, an increasing proportion of a hospital's PPS payment is based on the federal rate, and a declining proportion of its payment for each discharge is based on the provider's historical costs (the hospital-specific or HSP rate). Id.

The hospital-specific rate is derived from the historical costs that a hospital incurred in its base year under the cost-based reimbursement system. 42 C.F.R. 412.71. See also 42 U.S.C. 1395ww(b)(3)(A) and 1395ww(d)(1)(A) and (C). The fiscal intermediaries were responsible for calculating the hospital-specific rate prior to the beginning of each hospital's first PPS year, by estimating the reasonable cost otherwise reimbursable for the base year itself, and then making specified modifications to arrive at the hospital-specific rate. See 42 C.F.R. 412.71 and 412.72.

Given that reimbursement amounts in the base year are potentially subject to revision through administrative action and judicial review, the PPS regulations address the consequences of such revisions for the HSP rate. The Secretary's prospective relief rule, 42 C.F.R. 412.72(a)(3), authorizes, as a matter of administrative discretion, automatic prospective adjustments to the HSP

rate to take account of the recognition of additional base year costs in a final judicial decision or as the result of various administrative actions. However, retrospective changes are permitted only if the hospital can establish that the original estimation of base year costs was "unreasonable and clearly erroneous in light of the data available at the time the estimation was made." 42 C.F.R. 412.72(b)(2).

On November 15, 1988, the United States Court of Appeals for the District of Columbia Circuit held in Georgetown II, supra, that when a provider secures a final court judgment on a legal challenge brought under the prior cost-based reimbursement system, the agency must give full effect to such judgments throughout the four-year transition period under PPS. The Court rejected the principles and procedures established by the Medicare regulations, which authorize automatic prospective adjustments to the hospital-specific rate to reflect newly recognized base year costs but permit retrospective relief only under limited circumstances.

The Government has decided not to file a petition for certiorari in the Georgetown II case. Instead, HCFA

acquiesces on a nationwide basis in the D.C. Circuit's decision, to the extent that the statutory requirements, 42 U.S.C. 1395oo, for administrative and judicial appeals are satisfied with respect to the provider's challenge to the hospital-specific rate under PPS, and where such HSP rate challenge is predicated on certain factors (described below) that pertain to the hospital's base year costs. Accordingly, HCFA is instructing the intermediaries to adjust the HSP rate throughout the four-year transition period to reflect a hospital's additional base year costs that are newly recognized as the result of these enumerated factors. (Similarly, HCFA is instructing its intermediaries to adjust downward the HSP rate to reflect any subsequently determined decrease in a hospital's base year costs.) Separate settlements such as may be made under the May 11, 1988 "HHS Settlement Offer -- Medicare Malpractice Insurance Costs Litigation," will, of course, be controlled by their own terms and will not be affected by the Georgetown I decision or by HCFA's nationwide acquiescence in the Georgetown II decision.

HCFA's nationwide acquiescence in the Georgetown II decision renders moot for lack of an actual case or controversy all pending (and not otherwise settled HSP rate) appeals that, first, satisfy the jurisdictional requirements imposed by 42 U.S.C. 1395oo

and that, second, request that the HSP rate be revised retroactively (or for the duration of the four-year transition period) to reflect additional base year costs that are (or will be) newly recognized as the result of: a final, nonappealable court judgment; the administrative actions identified in 42 C.F.R. 412.72(a)(3)(i); pending claims for reimbursement under the pre-1981 wage index component of the 1981 cost limits; or pending malpractice insurance cost reimbursement claims under the pre-1979 utilization method of a hospital that did not accept the May 11, 1988 "HHS Settlement Offer -- Medicare Malpractice Insurance Costs Litigation." HCFA is undertaking appropriate measures in the federal courts to have the above-described challenges to the HSP rate remanded to the agency for payment. Similar steps are being taken to achieve payment of reimbursement claims pending before the Deputy Administrator of HCFA, the PRRB, and the intermediaries that are controlled by HCFA's nationwide acquiescence in the Georgetown II decision.

IMPLEMENTATION: In order to resolve in an orderly manner pending administrative appeals that have been rendered moot by the Georgetown I and Georgetown II decisions and to facilitate payment of affected reimbursement claims (described above), the administrative tribunal (i.e., the

intermediary, the PRRB, or the Deputy Administrator of HCFA) before which such appeal is pending shall, first, determine whether the appeal satisfies the jurisdictional prerequisites imposed by 42 U.S.C. 1395oo; and, second, if the applicable jurisdictional requirements are satisfied, then a determination shall be made that the provider is entitled to payment of its reimbursement claims under the terms of this Ruling. In the event such a favorable determination is made in an appeal pending before the PRRB or the Deputy Administrator of HCFA, the appeal shall be remanded to the appropriate intermediary for payment.

HCFA recognizes that, given the substantial number of wage index, malpractice insurance cost, and HSP rate reimbursement appeals pending at the PRRB, it could be difficult for the PRRB to identify and decide which of the pending administrative appeals of these issues would be controlled by the Georgetown I and Georgetown II decisions, and also meet the jurisdictional requirements of 42 U.S.C. 1395oo. Thus, HCFA is authorizing an alternative procedure in order to facilitate the orderly disposition of wage index, malpractice insurance cost, and HSP rate reimbursement administrative appeals and to avoid any inordinate delay.

Under this alternative procedure, the provider may request the PRRB to remand a pending appeal of the above-described wage index, malpractice insurance cost, or HSP rate reimbursement issues to the intermediary for payment of the provider's reimbursement claims prior to the time that the PRRB determines whether the provider's reimbursement claims are controlled by the Georgetown I or Georgetown II decisions and whether such claims satisfy the jurisdictional requirements imposed by 42 U.S.C. 1395oo. The intermediary would assume, under this alternative procedure, the initial responsibility of determining whether the provider satisfied the jurisdictional requirements, 42 U.S.C. 1395oo, for appealing its reimbursement claims to the PRRB, and whether the provider is entitled to payment under this Ruling. If the provider is dissatisfied with the intermediary's determination under this alternative procedure that the provider failed to satisfy the applicable jurisdictional requirements or that it otherwise failed to qualify for payment under the terms of this Ruling, then it may resume its original PRRB appeal without prejudice.

RULING: It is HCFA's Ruling that the Supreme Court's decision in Georgetown I, supra, 109 S. Ct. 468 (1988) controls and thereby renders moot for lack of an actual

of an actual case or controversy appeals challenging the wage index component of the 1981 cost limits or the retroactive 1984 wage index rule, in addition to appeals challenging the 1979 malpractice rule or the 1986 malpractice rule for cost reporting periods beginning before May 1, 1986, provided that such appeals satisfy the jurisdictional requirements of 42 U.S.C. 1395oo, and provided further that the hospital did not accept the May 11, 1988 "HHS Settlement Offer -- Medicare Malpractice Insurance Costs Litigation," or otherwise settle.

Furthermore, it is HCFA's Ruling that the D.C. Circuit's decision in Georgetown II, supra, Nos. 88-5026 and 88-5040 (D.C. Cir. Nov. 15, 1988) controls and thereby renders moot for lack of an actual case or controversy all pending (and not otherwise settled HSP rate) appeals that, first, satisfy the jurisdictional requirements imposed by 42 U.S.C. 1395oo and that, second, request that the HSP rate be revised retroactively (or for the duration of the four-year transition period) to reflect additional base year costs that are (or will be) newly recognized as the result of: a final, nonappealable court judgment; the administrative actions identified in 42 C.F.R. 412.72(a)(3)(i); pending claims for reimbursement under the pre-1981 wage index component of the 1981 cost limits;

or pending malpractice insurance cost reimbursement claims under the pre-1979 utilization method of a hospital that did not accept the May 11, 1988 "HHS Settlement Offer -- Medicare Malpractice Insurance Costs Litigation."

Finally, it is HCFA's Ruling that in order to ensure that the foregoing Rulings will be implemented in an expeditious and orderly manner with respect to pending appeals in the federal courts of the above-described wage index, malpractice insurance cost, or HSP rate reimbursement issues, HCFA will take appropriate measures in the federal courts to obtain a remand to the agency for payment, or, as may be necessary, for further jurisdictional findings by the administrative tribunal. Similarly, it is HCFA's Ruling that for any claim or appeal of the above-described wage index, malpractice insurance cost, or HSP rate reimbursement issues that is pending administratively (i.e., before the Deputy Administrator of HCFA, the PRRB, or the intermediary) that administrative tribunal shall, first, determine whether the appeal satisfies the jurisdictional prerequisites, 42 U.S.C. §1395oo, and, second, if the applicable jurisdictional requirements are satisfied, then a determination shall be made that the provider is entitled to payment of its reimbursement claims under the terms of

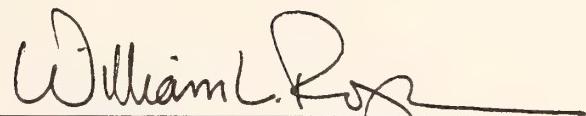
this Ruling. In the event such a favorable determination is made in an appeal pending before the PRRB or the Deputy Administrator of HCFA, the case shall be remanded to the appropriate intermediary for payment. Moreover, in order to provide an alternative means by which the provider may avoid the possibility of delay before the PRRB and to facilitate prompt payment of reimbursement claims subject to this Ruling, it is also HCFA's Ruling that if the provider requests the PRRB to remand to the intermediary for payment pursuant to this Ruling, an appeal of the above-described wage index, malpractice insurance cost, or HSP rate reimbursement issues -- before the PRRB has determined whether the appeal satisfied the jurisdictional requirements of 42 U.S.C. 1395oo and whether the provider's reimbursement claims are governed by this Ruling -- then the intermediary shall not oppose the provider's motion; the PRRB shall grant the provider's motion; and the intermediary shall make, subject to a determination as to whether the provider satisfies the applicable jurisdictional requirements and otherwise satisfies the terms of this Ruling, appropriate payments. However, if the intermediary ultimately determines that the provider failed to satisfy the jurisdictional prerequisites imposed by 42 U.S.C. 1395oo or otherwise

failed to qualify for payment pursuant to this Ruling, then the PRRB shall permit the provider to resume its original administrative appeal without prejudice.

EFFECTIVE DATE

This Ruling is effective January 26<sup>th</sup>, 1989.

DATED: 1.26.89



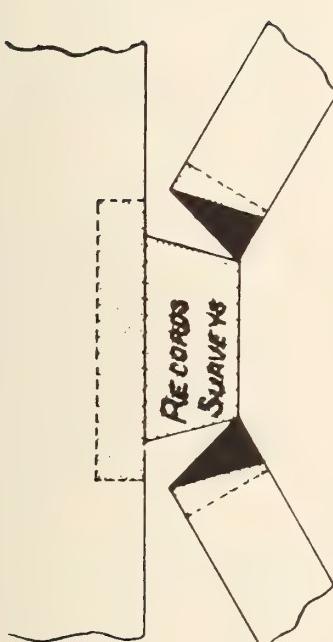
William L. Roper, MD  
Administrator, Health  
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stration



How to use these separators

Look for your reference letter. The far left column designated "TAB" will indicate proper tab position for that number or letter. Cut off and discard all tabs except the one you wish to retain. Example: Position number "10" would be found behind the fourth tab. Position letter "C" would be found behind the third tab.

TAB	(CHOOSE YOUR TAB)			
FIRST	V	O	H	A
SECOND	W	P	I	B
THIRD	X	Q	J	C
FOURTH	Y	R	K	D
FIFTH	Z	S	L	E
SIXTH		T	M	F
SEVENTH	U	N	G	



RECORDS  
SEARCH

TAB	(CHOOSE YOUR TAB)														
FIRST	98	91	84	77	70	63	56	49	42	35	28	21	14	7	0
SECOND	99	92	85	78	71	64	57	50	43	36	29	22	15	8	1
THIRD	100	93	86	79	72	65	58	51	44	37	30	23	16	9	2
FOURTH	94	87	80	73	66	59	52	45	38	31	24	17	10	3	
FIFTH	95	88	81	74	67	60	53	46	39	32	25	18	11	4	
SIXTH	96	89	82	75	68	61	54	47	40	33	26	19	12	5	
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# HCFA Rulings

Department of Health  
and Human Services

Health Care Financing  
Administration

Ruling No. HCFAR 87-4

Date June 1987

**HCFA Rulings** are decisions of the Administrator that serve as precedent final opinions and orders and statements of policy and interpretation. They provide clarification and interpretation of complex or ambiguous statutory or regulatory provisions relating to Medicare, Medicaid, Utilization and Quality Control Peer Review, and related matters.

**HCFA Rulings** are binding on all HCFA components, the Provider Reimbursement Review Board and Administrative Law Judges who hear Medicare appeals. These decisions promote consistency in interpretation of policy and adjudication of disputes.

This ruling reverses in part HCFAR 79-4 regarding Medicare payment for services with respect to which payment has been or could reasonably be expected to be made under the Federal Tort Claims Act.



**MEDICARE PROGRAM****Hospital and Supplementary Medical Insurance Benefits (Part A and B)****Payments Under Medicare and Awards Under the Federal Tort Claims Act**

HCFAR 87-4

**Purpose:** This Ruling modifies HCFA policy regarding Medicare payment for services with respect to which payment has been or could reasonably be expected to be made under the Federal Tort Claims Act.

This Ruling rescinds HCFAR 79-4 in part. For reader comprehension HCFAR 79-4 is included as an appendix.

**Citations:** Sections 1862(a)(3) and 1862(b)(1) of the Social Security Act (42 U.S.C. 1395y(a)(3) and 1395y(b)(1)); 42 CFR 401.108; 42 CFR 405.312, 405.322 and 405.324; 52 FR 26088; 52 FR 35145.

**Pertinent History:** A beneficiary entitled to hospital insurance benefits under Part A of title XVIII of the Social Security Act (the Act) was admitted to a hospital for the treatment of injuries received as the result of the negligence of a driver of a U.S. mail truck. The hospital and medical services were covered under Part A, and HCFA therefore reimbursed the hospital under title XVIII of the Act. Afterwards, the U. S. Postal Service approved an award for damages suffered by the beneficiary under the terms of the Federal Tort Claims Act (FTCA). This award included an amount to reimburse the beneficiary for hospital and medical expenses.

The question raised by this case is whether the payments awarded under the FTCA represent payment by a governmental entity and are of the type excluded under section 1862(a)(3) of the Act or whether they represent payment under a liability insurance policy or plan (including a self-insured plan) and are of the type excluded under section 1862(b)(1). (Generally, those sections mandate that no Medicare payment may be made for supplies or services that are paid for by a governmental entity or under a liability insurance policy or plan.) We originally addressed the issue of FTCA payments in 1969 as a Social Security Ruling (SSR 69-8). It was later published as a HCFA Ruling, HCFAR 79-4.

Where payment has been made to an individual under the FTCA for expenses incurred for medical and hospital services that are also covered under title XVIII of the Act, HCFAR 79-4 states that the services are not considered to have been "paid for directly or indirectly by a governmental entity" for purposes of the exclusion in section 1862(a)(3) of the Act. (Services for which payment is excluded under section 1862(a)(3) of the Act include services furnished to prisoners and to veterans for whom a State furnishes free care in a State-run home.) That portion of HCFAR 79-4 is affirmed, as there has been no subsequent change in the statute or regulations that would prompt a different conclusion. The implementing regulations of section 1862(a)(3) of the Act appear at 42 CFR 405.312.

The second part of HCFAR 79-4 states that the Act does not preclude payment under both the Medicare program and the FTCA. HCFA Ruling HCFAR 79-4 contains the following statement: ". . . there is nothing inconsistent with simultaneous reimbursement under the program and from other sources (with the sole exception of the priority of workmen's compensation payments), since title

XVIII is in the nature of social insurance." Consequently, the position taken in HCFAR 79-4 was that tort liability payments under the FTCA were to satisfy the injured party's claim for losses, and that, even though part of a payment might be to cover medical expenses that Medicare had paid or would pay, the injured party (Medicare beneficiary) could keep the entire FTCA payment. We are revising this portion of HCFAR 79-4 because such duplicate payments are inconsistent with the purpose of section 1862(b)(1) as amended since publication of HCFAR 79-4.

Because of HCFA's past policy that Medicare would pay for services without regard to FTCA payments, Medicare's payment has not been disputed. However, courts have considered whether FTCA payments should be paid without regard to the amount of any Medicare payments, applying a tort law equitable doctrine applicable in some states, called the "collateral source rule". The rule permits an injured party to recover medical expenses from a tortfeasor, despite reimbursement of those expenses to the injured party, if the reimbursement is from a "collateral source" and not from a tortfeasor. Generally, Medicare payments have been considered a collateral source and not been applied to reduce FTCA payments. See e.g., Berg v. United States, 806 F. 2d 978, 984-86 (10th Cir. 1986). Our changed policy, required by the legislative changes discussed below, will mean that Medicare payment will not be made, or if made, will be a conditional payment subject to recovery out of any FTCA award. See e.g., Buckner v. Heckler, 804 F.2d 258, 259 (4th Circ. 1986). Thus, cases such as Berg v. United States, supra, will no longer occur.

In recent years, Congress has amended Title XVIII of the Act to preclude payment by Medicare when certain other types of insurance, including tort liability

insurance, should be paying for the services. Title XVIII now recognizes a priority of other insurance coverage, including tort liability insurance, by providing in section 1862(b)(1) that:

Payment under this title may not be made with respect to any item or service to the extent that payment has been made, or can reasonably be expected to be made promptly (as determined in accordance with regulations), with respect to such item or service, under a workmen's compensation law or plan of the United States or a State or under an automobile or liability insurance policy or plan (including a self-insured plan) or under no fault insurance. Any payment under this title ... shall be conditioned on reimbursement to the appropriate Trust Fund ... when notice or other information is received that payment ... has been or could be made under such a law, policy, plan, or insurance. In order to recover payment made under this title ... the United States may bring an action against any entity which would be responsible for payment ... or against any entity (including any physician or provider) which has been paid ... under such law, policy, plan, or insurance, and may join or intervene in any action related to the events that gave rise to the need for such item or service. The United States shall be subrogated ... to any right of an individual or any other entity to payment ... under such a law, policy, plan, or insurance.

Under the regulations implementing the amended statute (42 CFR 405.322), payments under the FTCA are not explicitly mentioned as a form of tort liability insurance.<sup>1/</sup> However, they are clearly the type of duplicate payments that Congress wants to end. Reimbursement under both the Medicare program and the FTCA is inconsistent with that purpose.

<sup>1/</sup> On July 17, 1985, HCFA published a notice in the Federal Register (50 Fed. Reg. 28988) regarding HCFA's interpretation of certain changes made by the Deficit Reduction Act of 1984 (Pub. L. 98-369). The notice stated that those changes were self-implementing and notified the public that conflicting regulations would no longer apply pending clarification and revision to conform to the statutory changes. As applied until now to payments under the FTCA, 42 CFR 405.322 is not consistent with the provision of the law which limits Medicare payment when payment is also made under liability insurance. HCFA will modify the regulation to eliminate that inconsistency.

Furthermore, under current Medicare rules, amounts payable because of a tort liability by self-insured entities such as State and local governments, are taken into account before Medicare may make any payment for medical expenses stemming from the tort, except when the amounts are payable under the FTCA. Thus, in situations that are identical except for the fact that the tortfeasor in one instance is the Federal government and in the other is not, Medicare is the first payer in one (in the case involving the Federal government) but is second payer in the other (in the case involving any entity except the Federal government). Such a result is clearly at odds with the provision of amended section 1862(b)(1) of the Act limiting payment for expenses payable by liability insurance. Moreover, Congress has not expressed any intention to make an exception to §1862(b)(1) for FTCA payments.

This ruling also reverses the holding in HCFAR 79-4 that title XVIII provides neither subrogation rights nor any other right of reimbursement from third-party tortfeasors. Such rights were established by the amendments made to section 1862(b)(1) in 1980 by Pub. L. 96-499, and expressly clarified in 1984 by Pub. L. 98-369.

**Ruling:** It is held that reimbursement under the Medicare program when payment has been made or could reasonably be expected to be made promptly under the Federal Tort Claims Act is precluded to the extent of such payment by section 1862(b)(1) of the Social Security Act, which prohibits payment under Medicare for services for which payment has been made or can reasonably be expected to be made promptly under a liability insurance policy or plan (including a self-insured plan). It is further held that if Medicare has already made a payment for services

for which liability exists under the Federal Tort Claims Act, Medicare may recover its payments directly from the Federal entity responsible for such payments, or from anyone who has been paid by the responsible entity with respect to such services. This Ruling supersedes HCFAR 79-4 except for its conclusion that payments under the FTCA do not constitute payments by a "governmental entity" for purposes of the exclusion in 1862(a)(3) of the Act.

**APPENDIX: HCFAR 79-4**

**EFFECTIVE DATE:** June 18, 1987

SECTION 1803, 1862(a)(3) and 1862(b).—COVERED HOSPITAL SERVICES—SIMULTANEOUS REIMBURSEMENT UNDER TITLE XVIII OF SOCIAL SECURITY ACT AND AS PART OF AWARD UNDER FEDERAL TORT CLAIMS ACT

HCFAR-79-4

Where an award under the Federal Tort Claims Act for damages suffered by a Part A beneficiary included amounts to reimburse him for hospital and medical expenses also covered under title XVIII of the Social Security Act, held, (1) payments under the Federal Tort Claims Act do not constitute payments by a "governmental entity" for purposes of the exclusion in section 1862(a)(3) of the Social Security Act; (2) the Health Care Financing Administration is given no right to recover such amounts (i.e., the right of subrogation) or any other form of reimbursement from third-party tortfeasors by title XVIII of the Act; and (3) the beneficiary is permitted reimbursement under both title XVIII and the Federal Tort Claims Act, since there is nothing inconsistent with simultaneous reimbursement under the program and from other sources (with the sole exception of the priority of workmen's compensation payments), since title XVIII is in the nature of social insurance.

A beneficiary entitled to hospital insurance benefits under Part A of title XVIII of the Social Security Act was admitted to a hospital for the treatment of injuries received as the result of the negligence of a driver of a U.S. mail truck. The hospital and medical services were found covered under Part A, and reimbursement therefore was made to the provider-hospital pursuant to the provisions of title XVIII of the Social Security Act. Thereafter, an award for damages suffered by the beneficiary was approved by the Post Office Department under the terms of the Federal Tort Claims Act. This award included an amount to reimburse the beneficiary for hospital and medical expenses. However, the Post Office Department is withholding a portion of the award from the beneficiary, equal to the amount paid the hospital under title XVIII, pending advice as to its disposition.

Two questions are raised by the instant case: (1) whether the health care payments awarded under the Federal Tort Claims Act represent payment by a government entity and are therefore excluded from coverage under section 1862(a)(3) of the Social Security Act; and (2) whether title XVIII of the Social Security Act gives the health insurance program the right to recover from the third-party tortfeasor (Post Office Department) that portion of the tort claim award intended to reimburse the beneficiary for hospital and medical expenses incurred.

Where payment has been made to an individual under the Federal Tort Claims Act for expenses incurred for medical and hospital services which are also covered under title XVIII of the Social Security Act, such services are not considered to have been "paid for directly or indirectly by a governmental entity" for purposes of the exclusion in section 1862(a)(3) of the Social Security Act. Rather, such payments constitute payment of damages by a third-party tortfeasor for which reimbursement may also be made under title XVIII.

The right of the United States to recover from third-part tortfeasors financial expenditures made by it pursuant to legal requirement in connection with the medical care of an injured individual must devolve from an act of Congress. (United States V. Standard Oil, 67 S. Ct. 1604 (1947)). As a consequence of the opinion of the Supreme Court in the Standard Oil case, there was enacted the Federal Medical Care Recovery Act, 42 U.S.C. 2651 et seq., which establishes a right in the United States to seek recovery from third-person tortfeasors for the reasonable value of medical services furnished directly by the Federal Government to an individual who suffered injury as a result of the action of such third persons. However, there are

no provisions in title XVIII of the Social Security Act establishing subrogation rights in the Secretary of Health, Education, and Welfare or otherwise authorizing him to accept reimbursement out of awards under the Federal Tort Claims Act for health insurance payments he made for services covered under Medicare.

In this regard, it may also be noted that only in respect to workmen's compensation does title XVIII of the Social Security Act recognize a priority of other insurance coverage by providing in section 1862(b) that:

Payment \* \* \* may not be made with respect to any item or service to the extent that payment has been made, or can reasonably be expected to be made \* \* \* with respect to such item or service, under a workmen's compensation law or plan of the United States or a State. Any payment under this title with respect to any item or service shall be conditioned on reimbursement to the appropriate Trust Fund established by this title when \* \* \* payment for such item or service has been made under such a law or plan.

Furthermore, the nature of title XVIII reimbursement as social insurance--in contrast to those "government payments" specified by the Federal Medical Care Recovery Act--is emphasized by the provision of section 1803 of the Social Security Act that:

Nothing contained in this title shall be construed to preclude any State from providing or any individual from purchasing or otherwise securing, protection against the cost of any health services.

Thus, it is specifically recognized that there is nothing inconsistent with simultaneous reimbursement to the beneficiary from sources other than title XVIII--with the sole exception of the above-quoted provision excluding title XVIII payment in the event of workmen's compensation coverage.

Accordingly, it is held that payments under the Federal Tort Claims Act do not constitute payments by a "governmental entity" for purposes of the exclusion in section 1862(a)(3) of the Social Security Act; title XVIII of the Social Security Act provides no right of subrogation or any other form of reimbursement from third-party tortfeasors; and, with the sole exception of the priority of workmen's compensation payments, there is nothing inconsistent with simultaneous reimbursement under the Medicare program and from other sources since title XVIII is in the nature of social insurance.

(X-refer to SSR 69-8)

**How to use these separators**

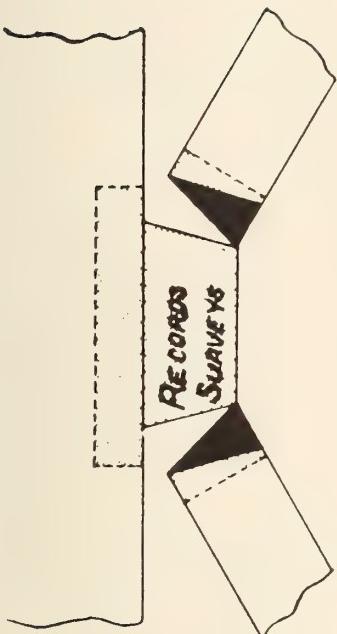
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# HCFA Rulings

Department of Health  
and Human Services

Health Care Financing  
Administration

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Ruling No HCFAR-87-2/87-3

Date April 1987

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These Rulings concern the Medicare Hospital Insurance program. HCFAR 87-2, effective April 9, 1987, addresses a Provider Reimbursement Review Board jurisdiction issue that was also the subject of HCFAR 86-2. HCFAR 87-3, also effective April 9, 1987, relates to the inclusion of labor/delivery room days in the calculation of inpatient days.



**Hospital Insurance Benefits (Part A)****Validity of Provider Reimbursement Manual Section 2345 Relating to the Inclusion of Labor/Delivery Room Days in the Calculation of Inpatient Days.**

HCFAR 87-3

**Purpose:** This Ruling announces HCFA's determination to follow the holdings of the courts of appeals for the Sixth, Eighth, Ninth, and District of Columbia Circuits with respect to claims that have been filed or could be filed within the jurisdiction of those circuits with respect to the validity of the labor/delivery room policy.

**Citations:** Section 1861(v) of the Social Security Act (42 U.S.C. 1395x(v)); 42 CFR 413.53; Provider Reimbursement Manual §2345; 52 FR 13873.

**Pertinent History:** The labor/delivery room policy, which is set forth in section 2345 of the Provider Reimbursement Manual, has been the subject of a substantial amount of litigation. This policy required that patients in a hospital's labor or delivery room at the census-taking hour be included in the inpatient count used to determine Medicare reimbursement for a hospital's general routine costs. The apportionment for general routine services is arrived at by multiplying the number of Medicare patient-days by the average per diem cost for all general routine services. The per diem figure is, in turn, computed by dividing total allowable routine costs by total inpatient days for the fiscal year. 42 CFR 413.53. Manual section 2345 clarifies this calculation by requiring that patients located in a hospital's labor or delivery room, or in any other ancillary area, at the

midnight census-taking hour be included in the count of total inpatient days for purposes of calculating the per diem cost of routine care.

Viewed in isolation, the policy of counting patients in labor and delivery rooms as inpatients advantages Medicare because of the relatively small number of maternity patients who are Medicare beneficiaries. Other accounting and allocation conventions disadvantage Medicare, however, because of different patient and cost distributions. These variations tend to average out and in the aggregate result in a proper allocation of Medicare and non-Medicare costs. The issue in the litigation has been the extent to which these general averaging principles authorize the labor/delivery room policy.

The validity of the policy has been considered by the courts of appeals in eight judicial circuits. In each of the cases the court declined to uphold the policy based on the evidence in the record before it. The courts did, however, offer HCFA the opportunity to justify the policy with additional evidence demonstrating that the advantages to Medicare from the labor/delivery room policy were offset by disadvantages from other allocation policies. The courts divided into two groups on what the additional evidence would have to show.

Half of the courts established a strict test that the additional evidence would have to meet to validate the labor/delivery room policy. These courts -- the Sixth, Eighth, Ninth, and District of Columbia Circuits -- held that the additional evidence necessary to justify the policy would have to identify cost distortions disadvantaging Medicare in other hospital

ancillary areas that offset the advantage to Medicare resulting from the labor/delivery room policy.<sup>1/</sup> HCFA cannot adduce evidence that meets the strict test established by these courts.

The other courts of appeals that considered the labor/delivery room policy allowed the agency much broader latitude to prove through additional evidence that there are cost allocation distortions adverse to Medicare that offset the effects of the labor/delivery room policy.<sup>2/</sup> Accordingly, HCFA has introduced evidence in new cases at the administrative level that demonstrates such an effect.

The initial decision in the District of Columbia Circuit, which adopted the strict test of what the additional evidence would have to prove, was ambiguous. The decision was not clear as to whether adoption of the strict test was based on the failure to raise the issue at the administrative level in that particular case, or whether the court was announcing a general principle that would apply in all cases. Recently, the

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<sup>1/</sup> University of Michigan v. Bowen, No. 86-1816 (6th Cir. Feb. 26, 1987); Sioux Valley Hospital v. Heckler, 792 F. 2d 715 (8th Cir. 1986); Mount Zion Hospital and Medical Center v. Heckler, 758 F.2d 1346 (9th Cir. 1985); International Philanthropic Hospital v. Heckler, 724 F. 2d 1368 (9th Cir. 1984); St. Mary of Nazareth Hospital Center v. Heckler, 760 F. 2d 1311 (D.C. Cir. 1985); St. Mary of Nazareth Hospital Center v. Schweiker, 718 F. 2d 459 (D.C. Cir. 1983).

<sup>2/</sup> Central DuPage Hospital v. Heckler, 761 F. 2d 354 (7th Cir. 1985); Community Hospital of Roanoke Valley v. Heckler, 770 F. 2d. 1257 (4th Cir. 1985); Beth Israel Hospital v. Heckler, 734 F. 2d. 90 (1st Cir. 1984); Tarrant County Hospital District v. Heckler, No 83-1483 (5th Cir. 1984).

district court for the District of Columbia has interpreted the court of appeals' decision as intended to apply the strict test in all cases.<sup>3/</sup>

We have determined to accept the district court's interpretation of the D.C. Circuit's prior holding. Consequently, there are four circuits in which the courts have established an evidentiary standard with respect to the validity of the labor/delivery room policy that we are unable to satisfy. The purpose of this Ruling is to announce our acquiescence in those decisions within the jurisdiction of the relevant circuits. We will dispose of claims pending in those circuits, or that could be filed in those circuits, by excluding labor/delivery room days from the calculation of inpatient days for the hospitals and cost years affected.

Since all providers can ordinarily obtain judicial review in the District of Columbia, this policy applies to all claims still at the administrative level, unless a court remand order or statutory provision necessitates that judicial review be sought elsewhere than in one of the four affected circuits, or unless the provider states that it intends to seek judicial review elsewhere.<sup>4/</sup>

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<sup>3/</sup> Stormont-Vail Regional Medical Center v. Bowen, No. 85-4011 (D.D.C. Sept. 25, 1986).

<sup>4/</sup> Our acquiescence in this instance respecting providers who could bring suit within the D.C. Circuit should not be viewed as an indication that any D.C. Circuit ruling on a Part A Medicare provider claim automatically results in a change in national Medicare policy. See generally United States v. Stauffer Chemical Co., 464 U.S. 165 (1984).

Pursuant to this Ruling, Medicare fiscal intermediaries will determine the amounts due and make appropriate payments through normal procedures. Claims must, of course, meet all other applicable requirements. This includes the requirement for data adequate to document the claimed costs. As the intermediaries may require, hospitals must furnish appropriate documentation to substantiate the number of days claimed (see section 1815(a) of the Social Security Act and 42 CFR 413.20, 413.24(a), (c)). Claims that are not disclosed on the cost report or an accompanying document (claims based on so-called "self-disallowed" costs) are not eligible for payment and remain ineligible under this Ruling.<sup>5/</sup>

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<sup>5/</sup> Athens Community Hospital Inc. v. Schweiker, 686 F.2d 989 (D.C. Cir. 1982), revised 743 F.2d 1 (D.C. Cir. 1984); St. Mary of Nazareth Hospital v. Schweiker, 741 F.2d 1447 (D.C. Cir. 1984); Community Hospital of Roanoke Valley v. Heckler, 770 F.2d 1257 (4th Cir. 1985); Baptist Hospital East v. Bowen, 802 F.2d 860 (6th Cir. 1986); North Broward Hospital District v. Bowen, No. 85-6039 (11th Cir. Jan. 17, 1987); University of Cincinnati v. Bowen 809 F.2d 307 (6th Cir. 1987).

**Ruling:** In the case of otherwise proper claims made by providers that can obtain judicial review of those claims in the Sixth, Eighth, Ninth, or District of Columbia Circuits, the labor/delivery room policy set forth in section 2345 of the Provider Reimbursement Manual will not apply, and reimbursement will be determined by excluding labor/delivery room days from the calculation of inpatient days.

**Effective Date:** April 9, 1987

**Dated:** April 9, 1987

William L. Roper, M.D.  
Administrator, Health Care  
Financing Administration

**How to use these separators**

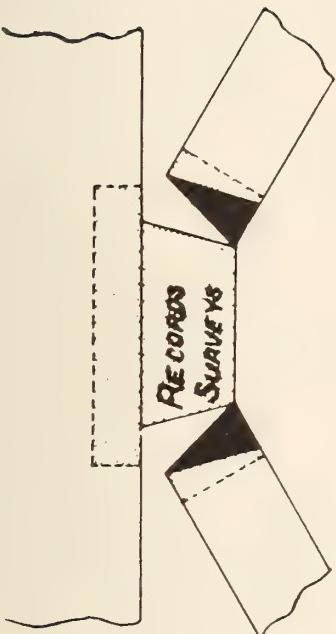
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**Hospital Insurance Benefits (Part A)**

**Provider Reimbursement Review Board Jurisdiction Over Challenges to the Application or the Validity of the Medicare Regulation Governing Apportionment of Malpractice Insurance Costs (42 CFR 413.56).**

HCFAR 87-2

**Purpose:** This Ruling states HCFA policy that the Provider Reimbursement Review Board now has jurisdiction to hear a provider's challenge to the application or validity of 42 CFR 413.56 even if the provider has not received a Notice of Program Reimbursement (NPR). Other jurisdictional prerequisites would continue to apply.

**Citations:** Section 1878 of the Social Security Act (42 U.S.C. 1395oo); 42 CFR Part 405, Subpart R; 52 FR 13874.

**Pertinent History:** On April 1, 1986, a new regulation governing the allocation of malpractice insurance costs was published (51 FR 11142) to supersede a regulation on the same subject that had been issued in 1979. The new regulation (42 CFR 413.56 as redesignated at 51 FR 34790, 34808) applies to cost reporting periods beginning on or after July 1, 1979. The public was offered an opportunity to comment on the 1986 regulation. A response to those comments was published on March 27, 1987 (52 FR 9833).

The new regulation generally results in reimbursement to providers that is greater than under the superseded rule. Medicare's fiscal intermediaries have implemented the new regulation on an interim basis with respect to many providers by paying them the estimated amount that will be owed when a final determination is made. The intermediaries,

however, have not yet made final determinations, and thus have not issued revised NPRs, in the case of most providers.

In HCFA Ruling 86-2, dated July 2, 1986, it was held that the Board has no jurisdiction to grant a hearing to a provider that wishes to challenge the application or the validity of the 1986 regulation with respect to a cost reporting period until such time as the intermediary issues to the provider an NPR or revised NPR reflecting application of that regulation. This Ruling reflected the provision of section 1878(a)(1)(A) of the Act, which requires receipt of the NPR before the Board has jurisdiction to consider a provider's appeal.

At the time that HCFA Ruling 86-2 was issued, it was anticipated that many providers would receive NPRs soon afterwards. Principally because of unexpected delays in issuing the final response to the many complex comments on the April regulation, however, the process of issuing revised NPRs also has been delayed.

A number of providers have indicated through court filings that they desire to challenge the validity of the 1986 regulation but have been frustrated in doing so by the absence of an NPR. It was not HCFA's intention to delay the availability of review. Nevertheless, we recognize that the unanticipated delays in issuing NPRs have made review unavailable.

Under section 1878(a)(1)(B) of the Act, a provider may obtain a Board hearing prior to receiving an NPR if it has not received the NPR "on a timely basis." Our regulations (42 CFR 405.1835(c)) define timeliness as

receipt of an NPR within 12 months after the provider has submitted its cost report. Since we are not requiring the submission of an amended cost report in the case of the 1986 regulation, this regulation may not literally apply. Nevertheless, it has now been 12 months since issuance of the 1986 regulation, and the timeliness considerations reflected in the statute and regulation should govern. We conclude that, under the circumstances present here, providers desiring to challenge the 1986 regulation have not received an NPR on a timely basis within the meaning of section 1878(a)(1)(B) if they have not already received one. Accordingly, the Board has jurisdiction to hear such cases if the other prerequisites for review have been satisfied. A provider may, of course, at its option await receipt of its NPR before seeking Board review.

**Ruling:** It is held that any provider seeking to challenge the 1986 malpractice rule has not received an NPR on a timely basis if an NPR has not yet been issued. Accordingly, the jurisdictional requirement of section 1878(a)(1) of the Act for Board review is satisfied.

**Effective Date:** April 9, 1987

**DATED:** April 9, 1987

William L. Roper, M.D.  
Administrator, Health Care  
Financing Administration



How to use these separators

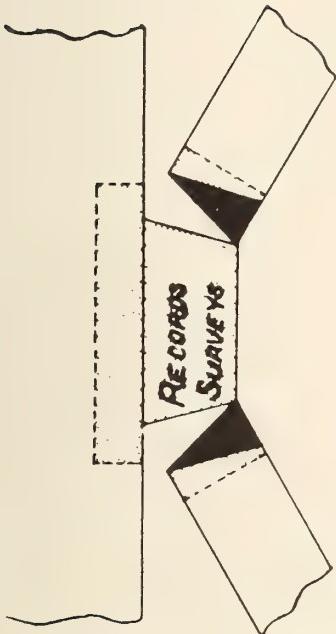
Look for your reference letter. The far left column designated "TAB" will indicate proper tab position for that number or letter. Cut off and discard all tabs except the one you wish to retain. Example: Position number "10" would be found behind the fourth tab. Position letter "C" would be found behind the third tab.

**TAB** (CHOOSE YOUR TAB)

FIRST	V	O	H	A
SECOND	W	P	I	B
THIRD	X	Q	J	C
FOURTH	Y	R	K	D
FIFTH	Z	S	L	E
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FIRST	98	91	84	77	70	63	56	49	42	35	28	21	14	7	0
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THIRD	100	93	86	79	72	65	58	51	44	37	30	23	16	9	2
FOURTH		94	87	80	73	66	59	52	45	38	31	24	17	10	3
FIFTH		95	88	81	74	67	60	53	46	39	32	25	18	11	4
SIXTH		96	89	82	75	68	61	54	47	40	33	26	19	12	5
SEVENTH		97	90	83	76	69	62	55	48	41	34	27	20	13	6





# HCFA Rulings

Department of Health  
and Human Services

Health Care Financing  
Administration

Ruling No. HCFAR 87-1

Date April 1987

**HCFA Rulings** are decisions of the Administrator that serve as precedent final opinions and orders and statements of policy and interpretation. They provide clarification and interpretation of complex or ambiguous statutory or regulatory provisions relating to Medicare, Medicaid, Utilization and Quality Control Peer Review, and related matters.

**HCFA Rulings** are binding on all HCFA components, the Provider Reimbursement Review Board and Administrative Law Judges who hear Medicare appeals. These decisions promote consistency in interpretation of policy and adjudication of disputes.

This Ruling provides criteria that facilities must comply with in order to obtain approval for payment for heart transplants. It rescinds HCFAR 80-1, which excluded heart transplants from coverage under Medicare. Coverage as a result of this Ruling may be effective as early as October 17, 1986 under some circumstances, as specified in the effective date section.



**Hospital Insurance Benefits (Part A)****Criteria for Medicare Coverage of Heart Transplants****HCFAR 87-1**

**Purpose:** This Ruling rescinds HCFA Ruling HCFAR 80-1 that excluded coverage of heart transplants under the Medicare program. It also provides public notice of HCFA's new coverage policy for heart transplants.

**Citations:** Sections 1102, 1862(a)(1) and 1871 of the Social Security Act (42 U.S.C. 1302, 1395y(a)(1) and 1395hh), 52 FR 10935.<sup>1</sup>

**Ruling:** HCFAR 80-1 that excludes heart transplants from coverage under the Medicare program is rescinded. Facilities that wish to obtain coverage of heart transplants for their Medicare patients must submit an application and supply documentation showing their initial and ongoing compliance with each of the criteria. For facilities which are approved, Medicare will cover under Part A (Hospital Insurance) all medically reasonable and necessary inpatient services. Payment for these services generally will be made under the Diagnosis Related Group (DRG) classification code #103, "Heart transplants". Organ acquisition costs will be paid separately on a cost-reimbursement basis. Physician services, related to the transplant,

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**HCFAR 87-1-2**

as well as non-hospital services related to pre-and post-transplant care, will be covered under Part B (Supplementary Medical Insurance) and reimbursed on the basis of reasonable charges. In accordance with the provisions of section 9335(c) of OBRA, post-transplant care for covered transplants includes outpatient, self-administrable immunosuppressant drugs, such as cyclosporine, for a period of up to one year beginning with the date of discharge from the inpatient hospital stay during which the transplant was performed. If a Medicare beneficiary receives a covered heart transplant from an approved facility, reasonable and necessary services for followup care and for complications are covered, even if such services are furnished by a hospital that is eligible for Medicare reimbursement but is not specifically approved by Medicare for heart transplantation.

Medicare will not cover transplants or re-transplants in facilities which have not been approved as Medicare transplant facilities. If a Medicare beneficiary receives a heart transplant from a facility that is not approved by Medicare for heart transplantation, we will not cover any inpatient services associated with the transplantation procedure. Neither will we cover physician services associated with the transplantation procedure. Thus, payment will not be made for the performance of the transplant or for any other services which are incorporated into a global fee. However, after a beneficiary has been discharged from a hospital (which has not been approved by Medicare as a heart transplant center) in which he or she receives the heart transplant, medical and hospital services required as a result of the prior non-covered transplant may be covered in

a facility otherwise eligible for Medicare reimbursement when they are reasonable and necessary in all other respects. Thus, coverage will be provided for subsequent inpatient stays or outpatient treatment (exclusive of self-administrable immunosuppressive drugs) ordinarily covered by Medicare even if the need for treatment arose because of a previous non-covered heart transplant procedure. These services also will be covered for Medicare beneficiaries who were not beneficiaries at the time they received a heart transplant regardless of whether or not the transplant was performed at an approved facility.

Once a facility applies for approval and is approved as a heart transplant facility for Medicare purposes, it is obliged to report immediately to HCFA any events or changes which would affect its approved status. Specifically, a facility must report any significant decrease in its experience level or survival rates, the transplantation of patients who do not meet its patient selection criteria, the loss of key members of the transplant team, or any other major changes that could affect the performance of heart transplants at the facility. Changes from the terms of approval may lead to withdrawal of approval for Medicare coverage of heart transplants performed at the facility.

A facility that we approve as meeting the criteria set forth in this notice may seek Medicare payment from its Medicare intermediary for heart transplants performed on Medicare patients. For facilities receiving Medicare payment under the Medicare prospective payment system, we will use the DRG classification #103, "Heart transplants". We have

established a relative weight of 14.9944 for DRG 103 and a 51 day outlier threshold.

Heart acquisition costs will be reimbursed as a cost pass through.

The criteria that we will require facilities to meet in order to receive Medicare payment for heart transplantations follow.

A. Criteria for Facilities

1. Patient selection. A facility must have adequate written patient selection criteria and an implementation plan for their application. (Guidelines for patient selection criteria appear in section D. of this ruling.)
2. Patient management. A facility must have adequate patient management plans and protocols that include the following:
  - a. Detailed plans for therapeutic and evaluative procedures for the acute and long-term management of a patient, including commonly encountered complications. The basis for confidence in these plans must be stated.
  - b. The logistics of the plans for patient management and evaluation during the waiting and immediate post-discharge, as well as in-hospital, phases of the program.
  - c. The logistics of the plans for long-term management and evaluation, including education of the patient, liaison with the patient's attending physician, and the maintenance of active patient records for five years.
3. Commitment. A facility must make a sufficient commitment of resources and planning to the heart transplant program

to carry through its application. Indications of this commitment could include the following:

- a. Commitment of the facility to the heart transplant program is at all levels and broadly evident throughout the facility. (A cardiac transplantation program requires a major commitment of resources. These may intermittently include many other departments as well as the principal sponsoring departments.)
- b. The facility has both the expertise and the commitment for participation in medical, surgical, and other relevant areas, particularly cardiology, cardiovascular surgery, anesthesiology, immunology, infectious diseases, pulmonary diseases, pathology, radiology, nursing, and social services. The facility must identify individuals in these areas in order to achieve an identifiable and stable transplant team. Responsible medical/surgical members of the team must be board certified or eligible in their respective disciplines or have demonstrated transplantation competence irrespective of board status.
  - (1) The component teams must be integrated into a comprehensive team with clearly defined leadership and corresponding responsibility.
  - (2) The facility must have an active cardiovascular medical and surgical program. (General indicators

of this type of program would be a minimum of 500 cardiac catheterizations and coronary arteriograms annually, with the ability and willingness to do these procedures on an emergency basis, and a surgical group that has demonstrated low mortality rates in an active open heart surgical program involving at least 250 procedures a year.) The surgical team responsible for transplantation must be an identified, stable group.

- (3) The anesthesia service must identify a team for transplantation that must also be available at all times.
- (4) The infectious diseases service must have both the professional skills and laboratory resources needed to discover, identify, and manage the complications from a whole range of organisms, many of which are uncommonly encountered in the usual infectious diseases laboratory.
- (5) The nursing service must identify a team or teams trained not only in hemodynamic support of the patient, but also in the special problems of managing immunosuppressed patients.
- (6) Pathology resources must be available for studying and reporting promptly the pathological responses to transplantation.

- (7) Adequate social service resources must be available.
  - (8) Mechanisms must be in place for managing the heart transplant program which assure that --
    - (A) Patient selection criteria are consistent with those set forth in the facility's written patient selection criteria;
    - (B) The facility is responsible for the ethical, and medical considerations involved in the patient selection process and application of patient selection criteria.
  - (9) Adequate plans exist for organ procurement meeting legal and ethical criteria, as well as yielding viable transplantable organs in reasonable numbers.
4. Facility plans. The facility must have overall facility plans, commitments, and resources for a program that will assure a reasonable concentration of experience; specifically, 12 or more cardiac transplantation cases per year. This level of activity must be shown feasible and likely on the basis of plans, commitments, and resources.
5. Experience and survival rates. The facility must demonstrate experience and success with a clinical organ transplantation program involving immunosuppressive technique. The evaluation of a facility's experience and survival rates will be made on patients transplanted since January 1, 1982.

The facility must have an established cardiac transplantation program with documented evidence of 12 or more patients in each of the two preceding 12-month periods and twelve patients prior to that but since January 1, 1982. Such programs are deemed to have the potential for acceptable data bases for estimating survival.

The applicant facilities will be required to report experience and survival rates as of a given point in time. That point in time must be within 90 days of the date we receive the application and will be referred to as the fiducial date. The fiducial date for experience and survival results must be the same and it must be stated.

Survival rates may be influenced by many factors, including random chance and patient selection. However, most authorities agree that a patient who is not free of adverse prognostic factors warrants cardiac transplantation only if he or she has a reasonable prognosis and the donor heart cannot be used in a patient who is a good candidate with at least a moderately urgent need and who is in reasonable geographic proximity. Initially, the facility must demonstrate actuarial survival rates of 73 percent for one year and 65 percent for two years for patients who have had heart transplants since January 1, 1982 at that facility. In reporting their actuarial survival rates, facilities must use the Kaplan-Meier technique. The

following definitions and rules also must be used:

- a. The date of transplantation must be the starting date for calculation of the survival rate.
- b. For those dead, the date of death is used if known. If the date of death is unknown, it must be assumed as one day after the date of the last ascertained survival.
- c. For those who have been ascertained as surviving within 60 days before the fiducial date, survival is considered to be the date of last ascertained survival, except for patients described in paragraph (e) below.
- d. Any patient who is not known to be dead but whose survival cannot be ascertained to a date that is within 60 days before the fiducial date, must be considered as "lost to followup" for the purposes of this analysis.
- e. Any patient transplanted between 61 and 120 days before the fiducial date must be considered as "lost to followup" if he or she is not known to be dead or his or her survival has not been ascertained for at least 60 days before the fiducial date. Any patient transplanted within 60 days before the fiducial date must be considered as "lost to followup" if he or she is not known to be dead or his or her survival has not been ascertained on the fiducial date.
- f. A facility must submit its survival analyses using the assumption that each patient in the "lost to followup"

category, (according to the criteria A.5.d. or e. above) died one day after the last date of ascertained survival. However, a facility may submit an additional analyses that reflects each patient in the "lost to followup" category as alive at the date of the last ascertained survival.

In addition to reporting actuarial survival rates, the facility must submit the following actual information on every Medicare and non-Medicare patient who received a heart transplant between January 1, 1982 and the date of the application:

- o Transplant number.
- o Age.
- o Sex.
- o Date of transplant.
- o Date of most recent ascertained survival.
- o Date of death.
- o The category of each patient (that is: living, dead, or "lost to followup" according to the criteria A.5.d. or e. above).

Unique patient identifiers are not needed. The facility may submit additional information on any of the cases that it would like the expert consultants to consider in their reviews.

Although we are not requiring that these data be submitted in a particular format, our review will be facilitated if the data are submitted as follows:

- o Data are tabulated in seven columns, with data for each patient appearing as one line and listed in the sequence of date of transplant.
  - o The fiducial date should appear on each page.
  - o The transplant numbers listed may be existing heart transplant numbers used by the applicant facility. If so, the basis for any missing numbers should be explained.
  - o The tabulation should include no more than these required data. If more data are provided, they should be through additional tables or supplemental explanation.
6. Maintenance and submission of data. The facility must agree to maintain and routinely submit to HCFA in a standard format prescribed by HCFA, summary data about patients selected, protocols used and short-and long-term outcome on all patients undergoing cardiac transplantation, not only those for whom payment under Medicare is sought. (Such data are necessary to provide a data base for an ongoing assessment of cardiac transplantation and to assure that approved facilities maintain appropriate patient selection criteria, adequate experience levels and satisfactory patient outcomes.) In addition, facilities must agree to notify HCFA immediately of any change related

to the facility's transplant program that could affect the health or safety of patients selected for covered Medicare heart transplants or which would otherwise alter specific elements in their application. For example, a facility must report any significant decrease in its experience level or survival rates, the loss of key members of the transplant team, or the transplantation of patients who do not meet the facility's patient selection criteria.

Facilities not approved for Medicare covered heart transplants are not required to maintain summary data in standard format. However, if and when these facilities apply for Medicare approval, they will be required to submit such data for all patients receiving a heart transplant beginning 30 days after being notified of our data requirements. We plan to issue instructions to all hospitals regarding the required summary data in the near future.

7. Organ procurement. The facility must operate or participate in an organ procurement program to obtain donor organs.
  - a. If a cardiac transplantation center utilizes the services of an outside organ procurement agency to obtain donor organs, it must have a written arrangement covering these services. The cardiac transplantation center must notify the Secretary in writing within 30 days of terminating such arrangements.

- b. "Organ procurement agency" is defined as an organization that meets the criteria of section 371(b) of the Public Health Service Act.
- 8. Laboratory services. The facility must make available, directly or under arrangements, laboratory services to meet the needs of patients. Laboratory services are performed in a laboratory facility approved for participation in the Medicare program.

B. Process for Review and Approval of Facilities

The approval of facilities will be based on a careful review of the materials submitted regarding their experience, survival rates, and expertise, as well as their commitment to the heart transplant program. We will conduct the review with the aid and advice of individual non-Federal, expert consultants in relevant fields. Generally, the consultants will have the responsibility of reviewing applications at the request of HCFA, making recommendations to HCFA on a timely basis concerning qualified facilities, and supporting each recommendation with written documentation. Consensus of the consultants is not required. The individual consultants will report to us on their findings with respect to individual applications and will provide the basis for decisions as to the approval or disapproval of such applications.

In approving facilities, we will compare the facility's submission against the criteria specified in this notice. The approval granted will be for a three year period and extensions of approval will require submission of a continuation application and will not be automatic.

In addition to reviewing applications, the individual expert consultants may propose specific changes to the coverage criteria. Finally, in certain limited cases, exceptions to the strict criteria proposed may be warranted if there is justification and if the facility ensures our objectives of safety and efficacy. Under no circumstances will exceptions be made for facilities whose transplant programs have been in existence for less than two years, and applications from consortia will not be approved. In these two cases, disapprovals will be made by HCFA and will not require prior reviews by the expert consultants. Additionally, exceptions on the basis of geographic considerations will not be granted.

C. Application Procedure

In order to facilitate the approval of qualified facilities, we announced in the proposed notice that we would begin accepting and reviewing applications from facilities that believed they were qualified based on the proposed criteria. Because the applications will be approved only on the basis of the criteria published in this final notice, facilities, which have submitted applications prior to the publication date of this final ruling ( April 6, 1987 ), have the opportunity to submit any necessary revision and additions to their applications.

A facility that seeks retroactive approval must show that it met the experience and survival criteria on the date to which it seeks retroactive approval, as well as show its experience and survival to the stated fiducial date.

The applications procedure is as follows:

1. An original and two copies of the application must be submitted on 8 1/2 by 11 inch paper, signed by a person authorized to do so. The facility must be a participating hospital under Medicare and must specify its provider number, and the name and telephone number of an individual we could contact should we have questions regarding the application.
2. Information and data must be clearly stated, well organized and appropriately indexed to aid in its review against the criteria specified in this notice. Each page must be numbered.
3. To the extent possible, the application should be organized into eight sections corresponding to each of the eight major criteria and addressing, in order, each of the sub-criteria identified.
4. The application should be mailed to the address below in a manner which provides the facility with documentation that it was received by us.

Administrator  
Health Care Financing Administration  
c/o Office of Executive Operations  
Room 777 East High Rise  
6325 Security Blvd.  
Baltimore, Maryland 21207

**D. Guidelines for Patient Selection Criteria**

Included in section A., Criteria for Facilities, is the requirement that a facility must have adequate written patient selection criteria and an implementation plan for their application.

**HCFAR 87-1-16**

Such criteria should include or be comparable to, but need not be limited to, the guidelines below that indicate the type of factors or areas we would like to see addressed. We expect to disapprove any facility that departs so significantly from the guidelines that Medicare beneficiaries would be placed at risk.

1. Patient selection criteria must be based upon both a critical medical need for transplantation and a maximum likelihood of successful clinical outcome.
2. The patient must have a very poor prognosis (for example, less than a 25 percent likelihood of survival for six months) as a result of poor cardiac status, but must otherwise have a good prognosis.
3. All other medical and surgical therapies that might be expected to yield both short- and long-term survival (for example, 3 or 5 years), comparable to that of cardiac transplantation, must have been tried or considered.
4. Many factors must be recognized at the present time to exert an adverse influence on the outcome after cardiac transplantation. The manner and extent to which adverse risk is translated into contraindication varies. A patient who meets patient selection criteria under section D. 2., 3., and 5., and is free of the adverse factors under this section 4a. and b., is considered a good candidate for cardiac transplantation. Some experts would not require freedom from all adverse

factors under this section 4b. We recognize that some who may not be considered "good candidates" may also benefit, but the likelihood or extent of benefit is significantly less.

a. Strongly adverse factors include:

- (1) Advancing age; for example, a patient beyond 53 to 57 years of age (the mid-50's). Until not long ago, limited experience with patients over age 50 showed that these patients had both impaired capacity to withstand post-operative and immunosuppressive complications and lessened survival. More recently, carefully selected patients through age 55 have had good survival experience; but experience with patients beyond age 55 is limited. The selection of any patient for transplantation beyond age 50 must be done with particular care to ensure an adequately young "physiologic" age and the absence or insignificance of coexisting disease.
- (2) Severe pulmonary hypertension (because of the limited work capacity of the typical donor right ventricle which is an important consideration in orthotopic cardiac transplantation). Generally, pulmonary vascular resistance above 5 Wood units or pulmonary artery systolic pressure over 65 mm Hg is

a serious adverse factor. However, these patients may be acceptable if a pulmonary vasodilator drug reduces both pulmonary vascular resistance below 3 Wood units and pulmonary artery systolic pressure below 50 mm Hg.

- (3) Renal or hepatic dysfunction not explained by the underlying heart failure and not deemed reversible (because of the nephrotoxicity and hepatotoxicity of cyclosporine). For patients who are to receive azathioprine and high-dose corticosteroid rather than cyclosporine, a slightly higher level of hepatic or renal dysfunction is acceptable, but substantial dysfunction is still a contraindication (because of the likelihood of early exacerbation postoperatively and because of interference with immunosuppressive regimens).
- (4) Acute severe hemodynamic compromise at the time of transplantation if accompanied by compromise or failure of one or more vital end-organs (because of a substantially less favorable prognosis for survival than for the average transplant recipient).
- (5) Symptomatic peripheral or cerebrovascular disease (because of accelerated progression in some patients after cardiac transplantation and on chronic corticosteroid treatment).

- (6) Chronic obstructive pulmonary disease or chronic bronchitis (because of poor postoperative course and likelihood of exacerbation of infection with immunosuppression).
- (7) Active systemic infection (because of the likelihood of exacerbation with initiation of immunosuppression).
- (8) Recent and unresolved pulmonary infarction, pulmonary roentgenographic evidence of infection, or of abnormalities of unclear etiology (because of the likelihood that this represents pulmonary infection).
- (9) Systemic hypertension, either at transplantation or prior to development of end-stage heart disease, that required multi-drug therapy for even moderate control (for example, multidrugs to bring diastolic pressure below 105 mm Hg) for patients who would be on cyclosporine protocols (because of the substantial exacerbation of hypertension with cyclosporine and the difficulty of its management).
- (10) Any other systemic disease considered likely to limit or preclude survival and rehabilitation after transplantation.

- (11) Cachexia, even in the absence of major end organ failure (because of the significantly less favorable survival of these patients).
- (12) The need for or prior transplantation of a second organ such as lung, liver, kidney, or marrow (because this represents the coexistence of significant disease, and because multi-organ transplantation must still be considered experimental).
- (13) A history of a behavior pattern or psychiatric illness considered likely to interfere significantly with compliance with a disciplined medical regimen (because a lifelong medical regimen is necessary, requiring multiple drugs several times a day, with serious consequences in the event of their interruption or excessive consumption).
- (14) The use of a donor heart, that may have had its effectiveness compromised by such factors as the use of substantial vasopressors prior to its removal from the donor, its prolonged or compromised maintenance between the time of its removal from the donor and its implantation into the patient, or pre-existing disease.

- b. Other factors given less adverse weight by some experts but considered importantly adverse by others include:
  - (1) Insulin-requiring diabetes mellitus, in the judgment of most experts (because the diabetes is often accompanied by occult vascular disease and because the diabetes and its complications are exacerbated by chronic corticosteroid therapy; even current cyclosporine immunosuppression regimens require chronic long-term corticosteroid, though at a lower dose, and high dose corticosteroid is used in the treatment of acute rejection).
  - (2) Asymptomatic severe peripheral or cerebrovascular disease (because of accelerated progression in some patients after cardiac transplantation and on chronic corticosteroid treatment).
  - (3) Documented peptic ulcer disease (because of the likelihood of early postoperative exacerbation).
  - (4) Current or recent history of diverticulitis (which must be considered a source of active infection that may be exacerbated with the initiation of immunosuppressant).
- 5. Plans for long-term adherence to a disciplined medical regimen must be feasible and realistic for the individual patient.

**HCFAR 87-1-22**

**Effective Dates:** October 17, 1986 for those facilities which would have qualified as heart transplant facilities when the transplant was performed and whose applications are received by HCFA by July 6, 1987. The effective date of coverage for heart transplants performed at facilities applying after July 6, 1987 is the date the facility receives approval as a heart transplant facility from HCFA.

**Dated:** March 20, 1987

William L. Roper, M.D.  
Administrator, Health Care  
Financing Administration

# HCFA Rulings

Department of Health  
and Human Services

Health Care Financing  
Administration

Ruling No. HCFAR 87-1

Date April 1987

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MEDICARE PROGRAM

HCFAR 87-1-1

Hospital Insurance Benefits (Part A)

**Criteria for Medicare Coverage of Heart Transplants**

**HCFAR 87-1**

**Purpose:** This Ruling rescinds HCFA Ruling HCFAR 80-1 that excluded coverage of heart transplants under the Medicare program. It also provides public notice of HCFA's new coverage policy for heart transplants.

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## **HCFAR 87-1-4**

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- (3) The anesthesia service must identify a team for transplantation that must also be available at all times.
- (4) The infectious diseases service must have both the professional skills and laboratory resources needed to discover, identify, and manage the complications from a whole range of organisms, many of which are uncommonly encountered in the usual infectious diseases laboratory.
- (5) The nursing service must identify a team or teams trained not only in hemodynamic support of the patient, but also in the special problems of managing immunosuppressed patients.
- (6) Pathology resources must be available for studying and reporting promptly the pathological responses to transplantation.

- (7) Adequate social service resources must be available.
  - (8) Mechanisms must be in place for managing the heart transplant program which assure that --
    - (A) Patient selection criteria are consistent with those set forth in the facility's written patient selection criteria;
    - (B) The facility is responsible for the ethical, and medical considerations involved in the patient selection process and application of patient selection criteria.
  - (9) Adequate plans exist for organ procurement meeting legal and ethical criteria, as well as yielding viable transplantable organs in reasonable numbers.
4. Facility plans. The facility must have overall facility plans, commitments, and resources for a program that will assure a reasonable concentration of experience; specifically, 12 or more cardiac transplantation cases per year. This level of activity must be shown feasible and likely on the basis of plans, commitments, and resources.
5. Experience and survival rates. The facility must demonstrate experience and success with a clinical organ transplantation program involving immunosuppressive technique. The evaluation of a facility's experience and survival rates will be made on patients transplanted since January 1, 1982.

The facility must have an established cardiac transplantation program with documented evidence of 12 or more patients in each of the two preceding 12-month periods and twelve patients prior to that but since January 1, 1982. Such programs are deemed to have the potential for acceptable data bases for estimating survival.

The applicant facilities will be required to report experience and survival rates as of a given point in time. That point in time must be within 90 days of the date we receive the application and will be referred to as the fiducial date. The fiducial date for experience and survival results must be the same and it must be stated.

Survival rates may be influenced by many factors, including random chance and patient selection. However, most authorities agree that a patient who is not free of adverse prognostic factors warrants cardiac transplantation only if he or she has a reasonable prognosis and the donor heart cannot be used in a patient who is a good candidate with at least a moderately urgent need and who is in reasonable geographic proximity. Initially, the facility must demonstrate actuarial survival rates of 73 percent for one year and 65 percent for two years for patients who have had heart transplants since January 1, 1982 at that facility. In reporting their actuarial survival rates, facilities must use the Kaplan-Meier technique. The

following definitions and rules also must be used:

- a. The date of transplantation must be the starting date for calculation of the survival rate.
- b. For those dead, the date of death is used if known. If the date of death is unknown, it must be assumed as one day after the date of the last ascertained survival.
- c. For those who have been ascertained as surviving within 60 days before the fiducial date, survival is considered to be the date of last ascertained survival, except for patients described in paragraph (e) below.
- d. Any patient who is not known to be dead but whose survival cannot be ascertained to a date that is within 60 days before the fiducial date, must be considered as "lost to followup" for the purposes of this analysis.
- e. Any patient transplanted between 61 and 120 days before the fiducial date must be considered as "lost to followup" if he or she is not known to be dead or his or her survival has not been ascertained for at least 60 days before the fiducial date. Any patient transplanted within 60 days before the fiducial date must be considered as "lost to followup" if he or she is not known to be dead or his or her survival has not been ascertained on the fiducial date.
- f. A facility must submit its survival analyses using the assumption that each patient in the "lost to followup"

category, (according to the criteria A.5.d. or e. above) died one day after the last date of ascertained survival. However, a facility may submit an additional analyses that reflects each patient in the "lost to followup" category as alive at the date of the last ascertained survival.

In addition to reporting actuarial survival rates, the facility must submit the following actual information on every Medicare and non-Medicare patient who received a heart transplant between January 1, 1982 and the date of the application:

- o Transplant number.
- o Age.
- o Sex.
- o Date of transplant.
- o Date of most recent ascertained survival.
- o Date of death.
- o The category of each patient (that is: living, dead, or "lost to followup" according to the criteria A.5.d. or e. above).

Unique patient identifiers are not needed. The facility may submit additional information on any of the cases that it would like the expert consultants to consider in their reviews.

Although we are not requiring that these data be submitted in a particular format, our review will be facilitated if the data are submitted as follows:

- o Data are tabulated in seven columns, with data for each patient appearing as one line and listed in the sequence of date of transplant.
  - o The fiducial date should appear on each page.
  - o The transplant numbers listed may be existing heart transplant numbers used by the applicant facility. If so, the basis for any missing numbers should be explained.
  - o The tabulation should include no more than these required data. If more data are provided, they should be through additional tables or supplemental explanation.
6. Maintenance and submission of data. The facility must agree to maintain and routinely submit to HCFA in a standard format prescribed by HCFA, summary data about patients selected, protocols used and short-and long-term outcome on all patients undergoing cardiac transplantation, not only those for whom payment under Medicare is sought. (Such data are necessary to provide a data base for an ongoing assessment of cardiac transplantation and to assure that approved facilities maintain appropriate patient selection criteria, adequate experience levels and satisfactory patient outcomes.) In addition, facilities must agree to notify HCFA immediately of any change related

to the facility's transplant program that could affect the health or safety of patients selected for covered Medicare heart transplants or which would otherwise alter specific elements in their application. For example, a facility must report any significant decrease in its experience level or survival rates, the loss of key members of the transplant team, or the transplantation of patients who do not meet the facility's patient selection criteria.

Facilities not approved for Medicare covered heart transplants are not required to maintain summary data in standard format. However, if and when these facilities apply for Medicare approval, they will be required to submit such data for all patients receiving a heart transplant beginning 30 days after being notified of our data requirements. We plan to issue instructions to all hospitals regarding the required summary data in the near future.

7. Organ procurement. The facility must operate or participate in an organ procurement program to obtain donor organs.
  - a. If a cardiac transplantation center utilizes the services of an outside organ procurement agency to obtain donor organs, it must have a written arrangement covering these services. The cardiac transplantation center must notify the Secretary in writing within 30 days of terminating such arrangements.

b. "Organ procurement agency" is defined as an organization that meets the criteria of section 371(b) of the Public Health Service Act.

8. Laboratory services. The facility must make available, directly or under arrangements, laboratory services to meet the needs of patients. Laboratory services are performed in a laboratory facility approved for participation in the Medicare program.

B. Process for Review and Approval of Facilities

The approval of facilities will be based on a careful review of the materials submitted regarding their experience, survival rates, and expertise, as well as their commitment to the heart transplant program. We will conduct the review with the aid and advice of individual non-Federal, expert consultants in relevant fields. Generally, the consultants will have the responsibility of reviewing applications at the request of HCFA, making recommendations to HCFA on a timely basis concerning qualified facilities, and supporting each recommendation with written documentation. Consensus of the consultants is not required. The individual consultants will report to us on their findings with respect to individual applications and will provide the basis for decisions as to the approval or disapproval of such applications.

In approving facilities, we will compare the facility's submission against the criteria specified in this notice. The approval granted will be for a three year period and extensions of approval will require submission of a continuation application and will not be automatic.

In addition to reviewing applications, the individual expert consultants may propose specific changes to the coverage criteria. Finally, in certain limited cases, exceptions to the strict criteria proposed may be warranted if there is justification and if the facility ensures our objectives of safety and efficacy. Under no circumstances will exceptions be made for facilities whose transplant programs have been in existence for less than two years, and applications from consortia will not be approved. In these two cases, disapprovals will be made by HCFA and will not require prior reviews by the expert consultants. Additionally, exceptions on the basis of geographic considerations will not be granted.

**C. Application Procedure**

In order to facilitate the approval of qualified facilities, we announced in the proposed notice that we would begin accepting and reviewing applications from facilities that believed they were qualified based on the proposed criteria. Because the applications will be approved only on the basis of the criteria published in this final notice, facilities, which have submitted applications prior to the publication date of this final ruling (April 6, 1987), have the opportunity to submit any necessary revision and additions to their applications.

A facility that seeks retroactive approval must show that it met the experience and survival criteria on the date to which it seeks retroactive approval, as well as show its experience and survival to the stated fiducial date.

The applications procedure is as follows:

1. An original and two copies of the application must be submitted on 8 1/2 by 11 inch paper, signed by a person authorized to do so. The facility must be a participating hospital under Medicare and must specify its provider number, and the name and telephone number of an individual we could contact should we have questions regarding the application.
2. Information and data must be clearly stated, well organized and appropriately indexed to aid in its review against the criteria specified in this notice. Each page must be numbered.
3. To the extent possible, the application should be organized into eight sections corresponding to each of the eight major criteria and addressing, in order, each of the sub-criteria identified.
4. The application should be mailed to the address below in a manner which provides the facility with documentation that it was received by us.

Administrator  
Health Care Financing Administration  
c/o Office of Executive Operations  
Room 777 East High Rise  
6325 Security Blvd.  
Baltimore, Maryland 21207

D. Guidelines for Patient Selection Criteria

Included in section A., Criteria for Facilities, is the requirement that a facility must have adequate written patient selection criteria and an implementation plan for their application.

Such criteria should include or be comparable to, but need not be limited to, the guidelines below that indicate the type of factors or areas we would like to see addressed. We expect to disapprove any facility that departs so significantly from the guidelines that Medicare beneficiaries would be placed at risk.

1. Patient selection criteria must be based upon both a critical medical need for transplantation and a maximum likelihood of successful clinical outcome.
2. The patient must have a very poor prognosis (for example, less than a 25 percent likelihood of survival for six months) as a result of poor cardiac status, but must otherwise have a good prognosis.
3. All other medical and surgical therapies that might be expected to yield both short- and long-term survival (for example, 3 or 5 years), comparable to that of cardiac transplantation, must have been tried or considered.
4. Many factors must be recognized at the present time to exert an adverse influence on the outcome after cardiac transplantation. The manner and extent to which adverse risk is translated into contraindication varies. A patient who meets patient selection criteria under section D. 2., 3., and 5., and is free of the adverse factors under this section 4a. and b., is considered a good candidate for cardiac transplantation. Some experts would not require freedom from all adverse

factors under this section 4b. We recognize that some who may not be considered "good candidates" may also benefit, but the likelihood or extent of benefit is significantly less.

a. Strongly adverse factors include:

- (1) Advancing age; for example, a patient beyond 53 to 57 years of age (the mid-50's). Until not long ago, limited experience with patients over age 50 showed that these patients had both impaired capacity to withstand post-operative and immunosuppressive complications and lessened survival. More recently, carefully selected patients through age 55 have had good survival experience; but experience with patients beyond age 55 is limited. The selection of any patient for transplantation beyond age 50 must be done with particular care to ensure an adequately young "physiologic" age and the absence or insignificance of coexisting disease.
- (2) Severe pulmonary hypertension (because of the limited work capacity of the typical donor right ventricle which is an important consideration in orthotopic cardiac transplantation). Generally, pulmonary vascular resistance above 5 Wood units or pulmonary artery systolic pressure over 65 mm Hg is

a serious adverse factor. However, these patients may be acceptable if a pulmonary vasodilator drug reduces both pulmonary vascular resistance below 3 Wood units and pulmonary artery systolic pressure below 50 mm Hg.

- (3) Renal or hepatic dysfunction not explained by the underlying heart failure and not deemed reversible (because of the nephrotoxicity and hepatotoxicity of cyclosporine). For patients who are to receive azathioprine and high-dose corticosteroid rather than cyclosporine, a slightly higher level of hepatic or renal dysfunction is acceptable, but substantial dysfunction is still a contraindication (because of the likelihood of early exacerbation postoperatively and because of interference with immunosuppressive regimens).
- (4) Acute severe hemodynamic compromise at the time of transplantation if accompanied by compromise or failure of one or more vital end-organs (because of a substantially less favorable prognosis for survival than for the average transplant recipient).
- (5) Symptomatic peripheral or cerebrovascular disease (because of accelerated progression in some patients after cardiac transplantation and on chronic corticosteroid treatment).

- (6) Chronic obstructive pulmonary disease or chronic bronchitis (because of poor postoperative course and likelihood of exacerbation of infection with immunosuppression).
- (7) Active systemic infection (because of the likelihood of exacerbation with initiation of immunosuppression).
- (8) Recent and unresolved pulmonary infarction, pulmonary roentgenographic evidence of infection, or of abnormalities of unclear etiology (because of the likelihood that this represents pulmonary infection).
- (9) Systemic hypertension, either at transplantation or prior to development of end-stage heart disease, that required multi-drug therapy for even moderate control (for example, multidrugs to bring diastolic pressure below 105 mm Hg) for patients who would be on cyclosporine protocols (because of the substantial exacerbation of hypertension with cyclosporine and the difficulty of its management).
- (10) Any other systemic disease considered likely to limit or preclude survival and rehabilitation after transplantation.

- (11) Cachexia, even in the absence of major end organ failure (because of the significantly less favorable survival of these patients).
- (12) The need for or prior transplantation of a second organ such as lung, liver, kidney, or marrow (because this represents the coexistence of significant disease, and because multi-organ transplantation must still be considered experimental).
- (13) A history of a behavior pattern or psychiatric illness considered likely to interfere significantly with compliance with a disciplined medical regimen (because a lifelong medical regimen is necessary, requiring multiple drugs several times a day, with serious consequences in the event of their interruption or excessive consumption).
- (14) The use of a donor heart, that may have had its effectiveness compromised by such factors as the use of substantial vasopressors prior to its removal from the donor, its prolonged or compromised maintenance between the time of its removal from the donor and its implantation into the patient, or pre-existing disease.

- b. Other factors given less adverse weight by some experts but considered importantly adverse by others include:
  - (1) Insulin-requiring diabetes mellitus, in the judgment of most experts (because the diabetes is often accompanied by occult vascular disease and because the diabetes and its complications are exacerbated by chronic corticosteroid therapy; even current cyclosporine immunosuppression regimens require chronic long-term corticosteroid, though at a lower dose, and high dose corticosteroid is used in the treatment of acute rejection).
  - (2) Asymptomatic severe peripheral or cerebrovascular disease (because of accelerated progression in some patients after cardiac transplantation and on chronic corticosteroid treatment).
  - (3) Documented peptic ulcer disease (because of the likelihood of early postoperative exacerbation).
  - (4) Current or recent history of diverticulitis (which must be considered a source of active infection that may be exacerbated with the initiation of immunosuppressant).
- 5. Plans for long-term adherence to a disciplined medical regimen must be feasible and realistic for the individual patient.

**HCFAR 87-1-22**

**Effective Dates:** October 17, 1986 for those facilities which would have qualified as heart transplant facilities when the transplant was performed and whose applications are received by HCFA by July 6, 1987. The effective date of coverage for heart transplants performed at facilities applying after July 6, 1987 is the date the facility receives approval as a heart transplant facility from HCFA.

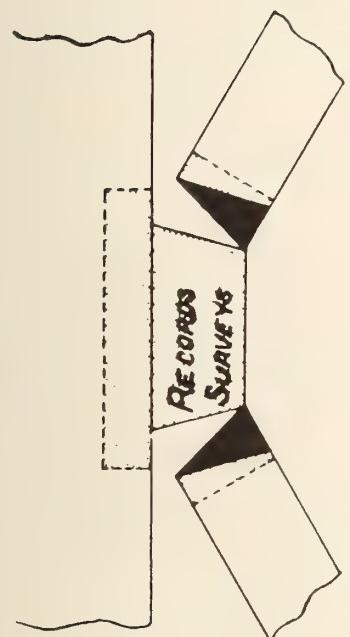
**Dated:** March 20, 1987

**William L. Roper, M.D.  
Administrator, Health Care  
Financing Administration**

**How to use these separators**

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# **HCFA Rulings**

Department of Health  
and Human Services

Health Care Financing  
Administration

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Ruling No. **HCFAR-86-2**

Date **July 1986**

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**HCFA Rulings** are decisions of the Administrator that serve as precedent final opinions and orders and statements of policy and interpretation. They provide clarification and interpretation of complex or ambiguous statutory or regulatory provisions relating to Medicare, Medicaid, Utilization and Quality Control Peer Review, and related matters.

**HCFA Rulings** are binding on all HCFA components, the Provider Reimbursement Review Board and Administrative Law Judges who hear medicare appeals. These decisions promote consistency in interpretation of policy and adjudication of disputes.

HCFA is currently in the process of transferring all **HCFA Rulings** that have been issued into a looseleaf form. This Ruling, which is effective July 2, 1986, is to be interfiled into the looseleaf **HCFA Rulings** when the latter is issued.



report," (2) the amount in controversy is at least \$10,000, and (3) the provider files a request for a hearing within 180 days after "notice of the intermediary's determination . . ." Medicare regulations at 42 CFR 405.1835 reiterate that a provider may obtain a hearing before the Board only if an "intermediary determination has been made with respect to the provider," the provider's hearing request is timely, and the amount in controversy is \$10,000 or more. See also 42 U.S.C. §1395oo(b); 42 CFR 405.1837 (group appeal jurisdictional prerequisites).

For cost reporting periods prior to the onset of the Prospective Payment System (PPS) and for non-PPS providers, "intermediary determination" is defined in the regulations as "a determination of the amount of total reimbursement due the provider, pursuant to §405.1803 following the close of the provider's cost reporting period, for items and services furnished to beneficiaries for which reimbursement may be made on a reasonable cost basis under Medicare for the period covered by the cost report." 42 CFR 405.1801(a)(1). "Amount in controversy" for purposes of appealing pre-PPS reimbursement determinations is computed under the regulations "by deducting the adjusted total reimbursable program costs due the provider on a reasonable cost basis from the total reimbursable costs claimed by the provider." 42 CFR 405.1839(a)(2). See also 42 CFR 405.1839(b)(2) (group appeals). Section 405.1807 of the regulations provides that an intermediary determination shall be final and binding on the parties to the determination unless it is revised in accordance with §405.1885, or a Board hearing is requested and a hearing decision rendered. Section 405.1885 provides that an intermediary decision shall be reopened and revised by the intermediary upon notification by the Health Care Financing Administration (HCFA) that the

decision is inconsistent with applicable law, regulations or general HCFA instructions. That section also permits reopening and revision of matters at issue on the cost report on motion of the intermediary or the provider, so long as the request to reopen is made within 3 years of the intermediary determination or Board hearing decision. Pursuant to this provision, an intermediary may in its discretion grant a provider's motion to reopen its determination with respect to certain matters at issue on the cost report while declining to permit reopening with respect to other matters affecting the NPR. Section 405.1889 of the regulations provides that "[w]here a revision is made in a determination or decision on the amount of program reimbursement," the revision "shall be considered a separate and distinct determination of decision to which the provisions of [§405.1835 and other sections relating to administrative and judicial review] are applicable."

On April 1, 1986, the Secretary published an interim final regulation governing the apportionment for Medicare reimbursement purposes of malpractice insurance costs incurred by Medicare providers in cost reporting periods beginning on or after July 1, 1979. 51 FR 11142. Promulgation of this new regulation, 42 CFR 405.457, effective May 1, 1986, rendered a nullity the 1979 malpractice rule which had previously governed the apportionment of malpractice insurance costs for cost reporting periods beginning on or after July 1, 1979, and the superseded regulation was removed. 51 FR 11195. As the preamble to §405.457 explains, intermediary determinations based upon the superseded regulation will be revised to apply the provisions of §405.457, subject to the rules of administrative finality and reopening. See 51 FR 11149, 11187-11188. Specifically, the preamble states in part:

The intermediary will automatically calculate reimbursement amounts for all open cost reports, including the cost reports for which the provider has timely appealed its reimbursement for malpractice insurance costs to the intermediary or the Provider Reimbursement Review Board (PRRB) in accordance with 42 CFR Part 405, Subpart R, of the Medicare regulations and that appeal is still pending. Within the reopening period specified in the regulations (that is, three years from the date of the NPR or last review decision), a provider may also request that a cost report determination be reopened for recalculation under this final rule.

51 FR 11149. Accordingly, if the intermediary has not yet issued a Notice of Program Reimbursement (NPR) with respect to a cost report, the intermediary will apply the provisions of 42 CFR 405.457 to the costs claimed for malpractice insurance. (To avoid disadvantaging any provider for periods beginning prior to May 1, 1986, however, adjustments will not be made to the extent that they would result in less reimbursement than would have been due under the superseded regulation. See 51 FR 11149.) If the intermediary has already issued an NPR for a cost reporting period using the now-defunct apportionment method contained in 42 CFR 405.452(a)(1)(ii) and the provider has requested a Board hearing on the issue of reimbursement for malpractice costs, and if such appeal is still pending before the Board, the intermediary will issue a revised NPR reflecting its application of §405.457. Similarly, if the Board has issued a decision following a hearing, or certified a challenge to the validity of the superseded regulation for expedited administrative review pursuant to 42 CFR 405.1842, and the provider has timely filed a complaint which is still pending in federal court challenging the application or the validity of 42 CFR 405.452(a)(1)(ii), the intermediary will issue a revised NPR reflecting application of §405.457. Finally, if the intermediary issued an NPR for a cost reporting

period reflecting adjustments resulting from application of the now-superseded §405.452(a)(1)(ii) and the provider did not timely request a Board hearing, the provider may within 3 years of the date of the NPR request reopening and a revised NPR to reflect application of §405.457; the intermediary's NPR for the affected cost reporting period will be reopened for the sole purpose of applying §405.457, unless the intermediary in its discretion agrees to reopen other matters at issue on the cost report, pursuant to 42 CFR 405.1885.

Under the Medicare statute and regulations, the intermediary's NPR provides the basis for Board review, as well as being the determinative factor in calculation of both the amount in controversy and the time limitation for filing a request for a hearing. Unless an NPR, reflecting an adjustment with which the provider disagrees, has been issued, the Board therefore lacks jurisdiction to hear a provider's appeal.

**Ruling:** Accordingly, it is held that the Board has no jurisdiction to grant a hearing to a provider that wishes to challenge the application or the validity of 42 CFR 405.457 with respect to a cost reporting period until such time as the intermediary issues to the provider an NPR or revised NPR reflecting application of that regulation (including in the case of those pre-May 1, 1986 cost reporting periods in which no adjustments are made due to the intermediary's determination that the superseded regulation yielded greater reimbursement, an NPR or revised NPR reflecting this determination under the new regulation). Similarly, the Board has no jurisdiction to entertain a provider's request for expedited administrative review to challenge the validity of §405.457 until such an NPR or revised NPR is issued. The Board may not entertain such a request

based on a provider's pending challenge to the application or validity of 42 CFR 405.452(a)(1)(ii), which no longer has effect; nor may the amount in controversy for purposes of determining Board jurisdiction be calculated by reference to the provider's estimates rather than by reference to the intermediary's final determination.

This result will not unduly delay the administrative and judicial review of provider claims for malpractice insurance costs, since intermediaries have already begun to issue tentative settlements under 42 CFR 405.457 in pending cases, and in many of these cases, revised NPRs will be issued within the next several weeks.

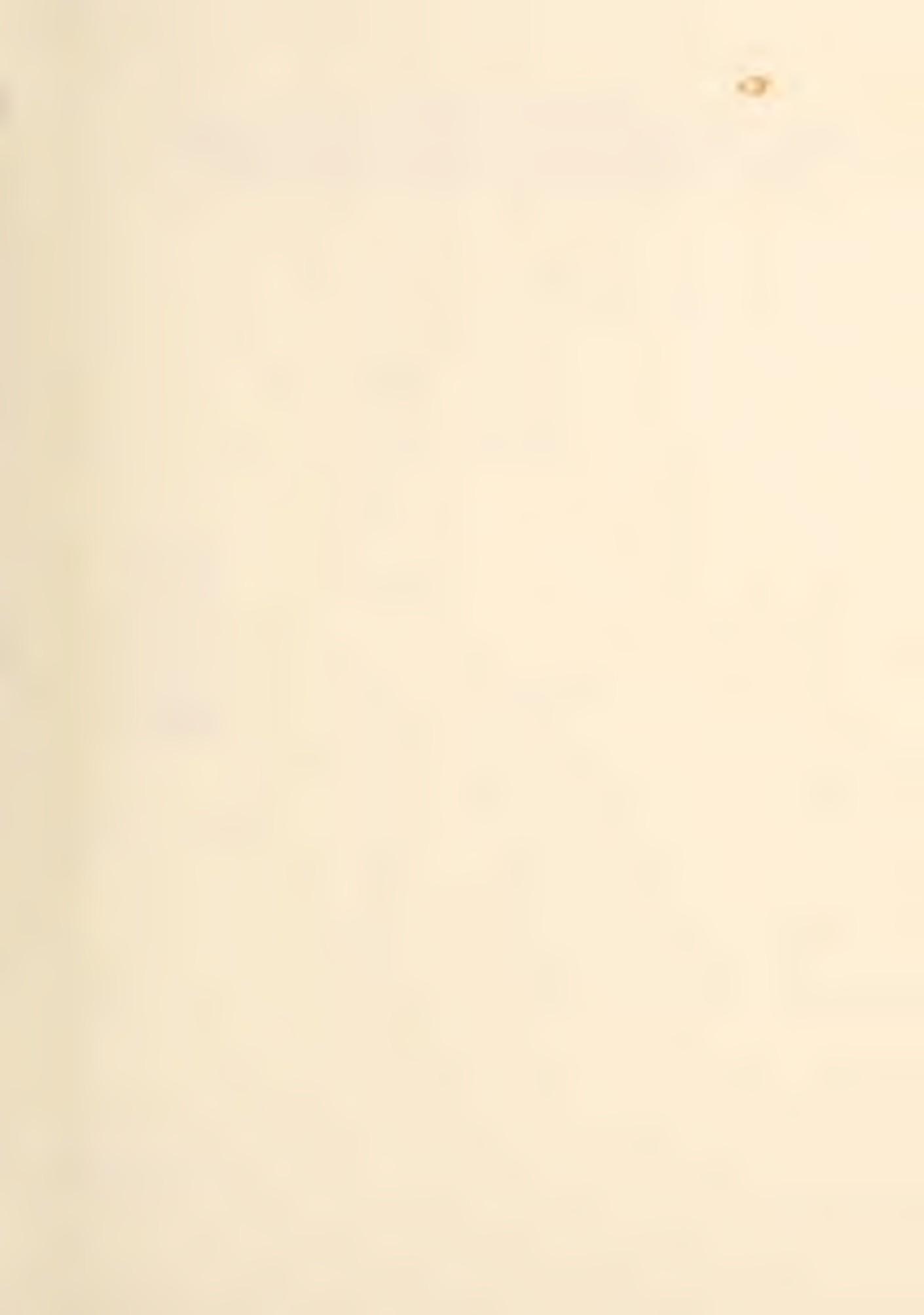
Moreover, for most cost reports to which the 1979 malpractice rule was originally applied and with respect to which the providers have submitted sufficient information to the intermediaries to facilitate the application of §405.457, HCFA anticipates that revised NPRs will be issued by fall 1986.

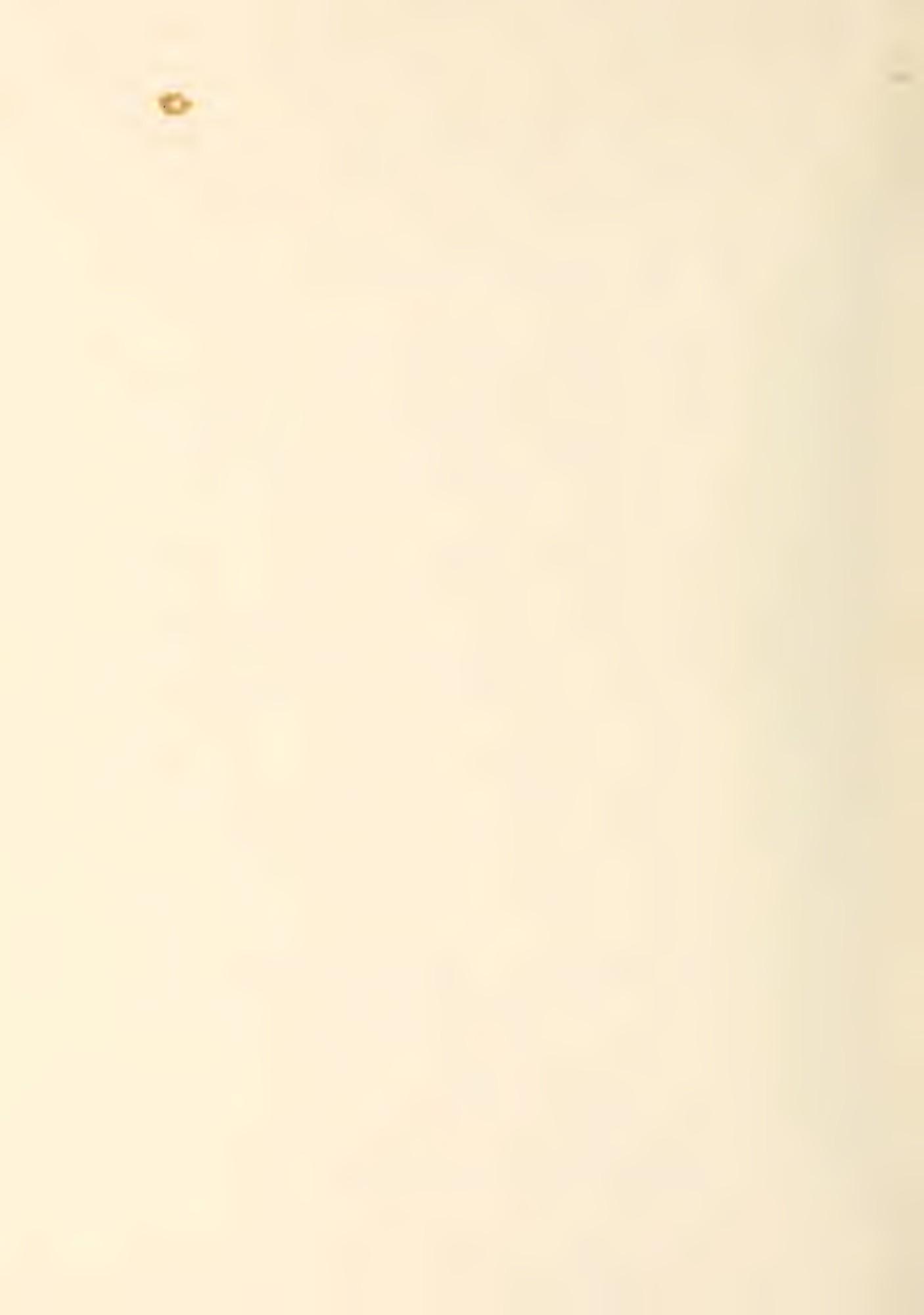
DATED: July 2, 1986

/s/ Glenn M. Hackbarth for  
William L. Roper, M.D.  
Administrator,  
Health Care Financing  
Administration

**Effective Date:** July 2, 1986







How to use these separators

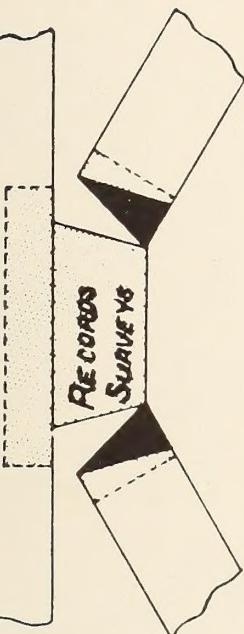
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